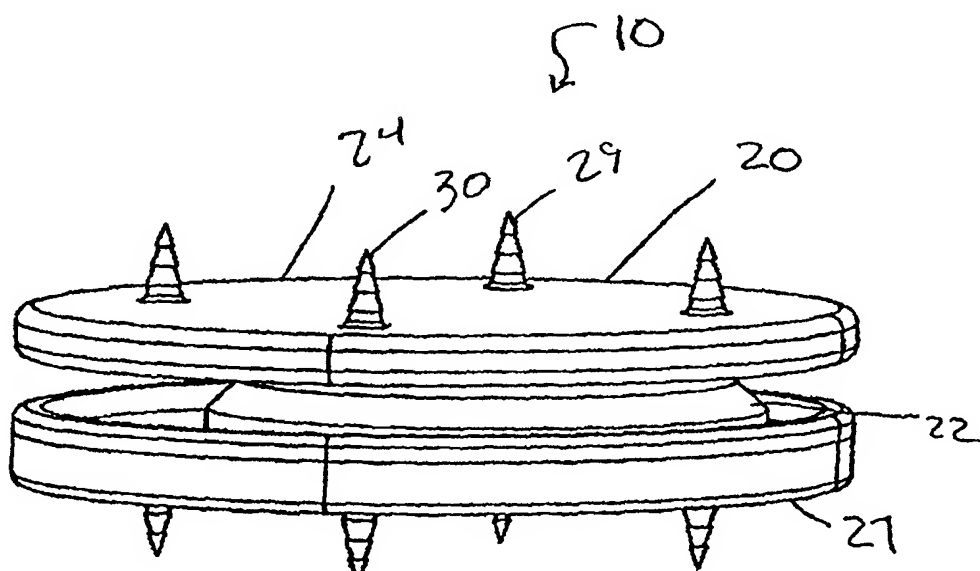


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(21) International Application Number: PCT/US00/06172 (22) International Filing Date: 9 March 2000 (09.03.00) (30) Priority Data: 09/266,369 11 March 1999 (11.03.99) US (71) Applicant: SULZER SPINE-TECH INC. [US/US]; 7375 Bush Lake Road, Minneapolis, MN 55439-2029 (US). (72) Inventors: ERICKSON, Richard, A.; 6229 Crescent Drive, Edina, MN 55436 (US). GRIFFITH, Steven, L.; 7691 Atherton Way, Eden Prairie, MN 55346 (US). (74) Agent: BRUESS, Steven, C.; Merchant & Gould P.C., P.O. Box 2903, Minneapolis, MN 55402-0903 (US).		(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, DZ, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (Utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: INTERVERTEBRAL DISC PROSTHESIS AND METHOD  (57) Abstract <p>The present invention is directed to intervertebral prosthetic devices and methods. The intervertebral prosthetic devices and methods of the invention provides a variable instantaneous axis of rotation. In general, the disclosed devices include two bearing surfaces, a first bearing surface being curved and a second bearing surface being planar. In some embodiments, the curved bearing surface provides at least three degrees of rotational freedom and the planar bearing surface provides at least two degrees of translational freedom and one degree of rotational freedom. Several embodiments with varying degrees of rotational or translational freedom are disclosed.</p>		

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INTERVERTEBRAL DISC PROSTHESIS AND METHOD

Field of the Invention

5 The present invention pertains to stabilization of an intervertebral disc space. More particularly, the invention pertains to prosthetic intervertebral disc devices and methods for stabilizing an intervertebral disc joint while providing joint mobility.

Background of the Invention

10 Chronic back problems can cause pain and disability for a large segment of the population. Frequently, the cause of back pain is traceable to diseased disc material between opposing vertebrae. When the disc material is diseased, the opposing vertebrae may be inadequately supported, resulting in persistent pain.

15 Surgical techniques have been developed to remove the diseased disc material and fuse the joint between opposing vertebral bodies. Arthrodesis of the intervertebral joint can reduce the pain associated with movement of an intervertebral joint having diseased disc material. Generally, fusion techniques involve removal of the diseased disc, drilling a bore for receiving a spinal fusion
20 implant and inserting the implant between the opposing vertebral bodies. Spinal fusion implants and related surgical instruments for implanting a fusion device are known and disclosed in, for example, U.S. Patent Nos. 5,741,253; 5,658,337; 5,609,636; 5,505,732; 5,489,308; 5,489,307; 5,484,437; 5,458,638; 5,055,104; 5,026,373; 5,015,247; and 4,961,740.

25 One disadvantage to intervertebral disc fusion is that the relative motion between the fused vertebrae is no longer possible, causing both stiffness in the spine and difficulties in the areas above and below the fused vertebrae. Thus, one alternative to fusing a diseased intervertebral joint space is to remove the diseased disc material and replace it with a prosthetic disc. Examples of prosthetic
30 disc devices are disclosed in, for example, U.S. Patent Nos. 4,759,766; 4,759,769; 5,258,031; 5,401,269; 5,425,773; 5,556,431 and 5,676,701. However, while such devices may provide greater mobility when compared to fused vertebrae, the mobility permitted by most known devices does not fully account for normal vertebral biomechanics.

35 Accordingly, there is a continuing need for intervertebral stabilization apparatuses and methods which provide mobility at the diseased intervertebral joint space. Moreover, there is a need for intervertebral stabilization methods which mimic normal intervertebral biomechanics.

Summary of the Invention

The present invention is directed to devices and methods for intervertebral stabilization which provide mobility at the diseased intervertebral joint. One advantageous feature of a device according to the invention is that it mimics normal intervertebral biomechanics by providing a variable instantaneous axis of rotation.

Throughout the specification, guidance may be provided through lists of examples. In each instance, the recited list serves only as a representative group. It is not meant, however, that the list is exclusive.

In general, an intervertebral prosthetic device (IPD) of the invention is an assembly including a first member for contacting a first vertebrae, a second member for contacting a second vertebrae and an intermediate member positioned between the first and second members. The assembly includes at least two bearing surfaces. A first bearing surface formed between the first member and the intermediate member and the second bearing surface formed between the second member and the intermediate member. At least one of the bearing surfaces is curved and at least one of the bearing surfaces is flat. The curved bearing surface can be spherical, cylindrical, ellipsoidal, oblong, etc.

In some embodiments, the curved bearing surface provides at least three degrees of rotational freedom. The linear bearing surface can provide at least two degrees of translational freedom and one degree of rotational freedom. The rotational and translational freedom of an IPD can also be selectively limited through arrangements disclosed herein.

Brief Description of the Drawings

FIG. 1 illustrates standard orientational planes of an XYZ coordinate system for describing rotational and translational movement of the spinal column;

FIGs. 2a-2c diagrammatically illustrate the variable instantaneous axis of rotation which occurs during anterior/posterior rotation of the lumbar vertebrae;

FIG. 3 is a perspective view of one embodiment of an intervertebral prosthetic device according to the invention;

FIG. 3a is a perspective view of an alternative embodiment of an intervertebral prosthetic device according to the invention;

FIG. 4 is an exploded perspective view of the intervertebral prosthetic device of FIG. 3;

FIG. 4a is an exploded perspective view of the intervertebral prosthetic device of FIG. 3a;

FIG. 5 is a top plan view of the intervertebral prosthetic device of FIG. 3;

5 FIG. 5a is a top plan view of the intervertebral prosthetic device of FIG. 3a;

FIG. 6 is a cross-section view through of the intervertebral prosthetic device of FIG. 5 taken through line 6-6;

10 FIG. 7 is a cross-section view through the intervertebral prosthetic device of FIG. 5 taken through line 7-7.

FIG. 8 is a cross-section of the intervertebral prosthetic device of FIG. 5 taken through line 7-7 as viewed from the left lateral aspect of a patient when in the neutral (standing) position;

15 FIG. 9 is the same view as FIG. 8 but when in extension (posterior rotation);

FIG. 10 is the same view as FIG. 8 but when in flexion (anterior rotation);

FIG. 11 is a top plan view of the intermediate piece of the intervertebral prosthetic device of FIG. 3;

20 FIG. 12 is a cross-section of the intermediate piece of FIG. 11 through line 12-12;

FIG. 13 is top plan view of an alternative embodiment of an intermediate piece;

25 FIG. 14 is a longitudinal cross-section view of the intermediate piece of FIG. 13 taken through line 14-14 ;

FIG. 15 is a transverse cross-section view of the intermediate piece of FIG. 13 taken through line 15-15;

FIG. 16 is a top plan view of an alternative embodiment of an intermediate piece;

30 FIG. 17 is a longitudinal cross-section view of the intermediate piece of FIG. 16 taken through line 17-17;

FIG. 18 is a transverse cross-section view of the intermediate piece of FIG. 16 taken through line 18-18;

35 FIG. 19 is a cross-section through an alternative embodiment of an intervertebral prosthetic device according to the invention;

FIG. 20 is a top plan view of an alternative embodiment of the linear surface of an end piece of an intervertebral prosthetic device of the invention;

FIG. 21 is a bottom plan view of one embodiment of an intermediate piece which cooperatively articulates with the end piece of FIG. 20;

FIG. 22 is a bottom perspective view of the intermediate piece of FIG. 21;

5 FIG. 23 is a longitudinal cross-section view through the end piece of FIG. 20 and intermediate piece of FIG. 22 when in cooperating arrangement;

FIG. 24 is a transverse cross-section view through the end piece and intermediate piece when in cooperating arrangement as in FIG. 23;

10 FIG. 25 is a bottom perspective view of an alternative embodiment for an intermediate piece;

FIG. 26 is a bottom plan view of the intermediate piece of FIG. 25;

FIG. 27 is a bottom perspective view of an alternative embodiment of an intermediate piece;

FIG. 28 is a bottom plan view of the intermediate piece of FIG. 27;

15 FIG. 29 is a diagrammatic side view of an intervertebral disc prosthesis;

FIG. 30 is a cross-section view through a first embodiment of a lordotic intervertebral prosthetic device;

20 FIG. 31 is a cross-section view through an alternative embodiment of a lordotic intervertebral prosthetic device;

FIG. 32 is a cross-section view through another embodiment of an intervertebral prosthetic device of the invention;

FIG. 33 is a cross-section view through another embodiment of an intervertebral prosthetic device of the invention.

25

Detailed Description of the Disclosure

The present disclosure is directed to intervertebral prosthetic devices and methods which provide rotational and translational movement of an intervertebral joint within physiological constraints. Thus, in many embodiments, 30 the devices and methods disclosed provide intervertebral joint mobility which mimics normal intervertebral joint mobility. In addition to other unique features, the prosthetic devices and methods disclosed provide a variable instantaneous axis of rotation regardless of whether the range of rotational movements is full or limited.

Throughout the disclosure standard terms are used to refer to the 35 orientation and relative location of vertebrae within the vertebral column. The principles, devices and methods disclosed herein are generally applicable to all vertebral mobility. However, for ease of understanding, the invention will be discussed with specific reference to the lumbar vertebrae. Nonetheless, it will be

appreciated that the devices and methods disclosed are also applicable for use with cervical and thoracic vertebrae.

Generally, normal movement between vertebral bodies which are spaced apart by a healthy intervertebral disc includes three types of rotational motion: anterior/posterior rotation (i.e. flexion/extension), lateral rotation (i.e. lateral bending) and axial rotation. FIG. 1 illustrates a human body within standard orientational planes of an x, y, z coordinate system. For purposes here, anterior/posterior rotation (i.e., flexion/extension) is rotation of the vertebral column in the sagittal plane 1. Right and left lateral bending is rotation of the vertebral column in the frontal plane 2 and axial rotation is rotation of the vertebral column around the y axis.

In addition, during rotation, translational movement also occurs. "Translational" movement is the movement which occurs between adjacent vertebrae in horizontal plane, 3. The amount of translational motion which can occur between adjacent vertebrae varies between individuals and, within a given individual, between vertebral body types.

The amount of translational movement which occurs between adjacent vertebrae during each type of rotation is greatest during flexion and extension, minimal during lateral bending, and essentially non-existent during axial rotation. The translational movement which occurs during flexion/extension causes the axis of rotation between adjacent vertebrae to shift anteriorly or posteriorly throughout the anterior/posterior range of motion. FIGs. 2a-2c diagrammatically illustrate an example of the shifting of the axis of rotation between two lumbar vertebrae L_a, L_b during flexion/extension. FIG. 2a shows the axis of rotation A_N between adjacent lumbar vertebrae L_a and L_b when in the neutral or standing position. Note that the axis of rotation A_N in this vertebral position is not midway between the anterior (A) and posterior (P) aspects of the vertebrae, but rather is located at about the posterior one third t_3 of the vertebrae. FIG. 2b illustrates the position of the axis of rotation A_F during anterior rotation or flexion. FIG. 2c illustrates the position of the axis of rotation A_E during posterior rotation or extension. At each of the positions of FIGs. 2a-2c the location of the axis of rotation has shifted relative to the anterior and posterior aspects of the vertebrae. The shifting of the axis of rotation is a translational movement approximately within the horizontal plane (FIG. 1). Each of the axes illustrated in FIGs. 2a-2c (A_N, A_F, A_E) represent an instantaneous axis of rotation ("IAR"). That is, FIGs. 2a-2c illustrate the axis of rotation between the vertebrae when the vertebrae are in the particular positions illustrated. The shifting location of the rotational axis between vertebrae during relative movement is referred to as a "variable instantaneous axis of rotation."

The intervertebral prosthetic devices and methods disclosed herein mimic the normal movement between adjacent vertebrae by providing a variable instantaneous axis of rotation throughout rotation of the vertebral column, particularly during flexion and extension. The devices and methods disclosed
5 provide greater rotational freedom by permitting at least one degree of translational freedom during rotation. In addition to biomechanical advantages related to patient movement, providing translational freedom throughout rotation reduces the shear forces which occur at the junction between the prosthetic device and the end plates of opposing vertebrae when translational freedom is constrained. Thus, the
10 likelihood of post-surgical expulsion or migration of the device is reduced.

A prosthetic device of the invention includes at least two bearing surfaces provided by three components, two components which attach to adjacent vertebrae and a third component which is positioned between the first two. Each of the first two components or end pieces have a bearing surface and a contact surface.
15 The third component or intermediate piece has at least two bearing surfaces. For clarity, the bearing surfaces of the components of the devices will be referred to as articular surfaces.

In use, the contact surface of each end piece engages the end plate of one of the adjacent vertebrae. Each of the articular surfaces of the intermediate piece
20 are configured to cooperatively fit with the articular surface of one of the end pieces. In general, a first articular surface of the intermediate piece is curved and a second articular surface is planar. The articular surface of the first end piece which is opposed to the first articular surface of the intermediate piece is curved and the articular surface of the second end piece which is opposed to the second articular
25 surface of the intermediate piece is planar. Thus, the prosthetic device includes a curved bearing surface comprised of the curved articular surfaces of one end piece and the intermediate piece and a planar bearing surface comprised of the planar articular surfaces of a second end piece and the intermediate piece.

In some embodiments, the curved bearing surface permits rotational
30 freedom in all directions, that is, rotation around the Y axis, in the sagittal plane, frontal plane and planes oblique to these planes. The planar bearing surface can permit rotational freedom around the Y axis as well as translational freed along the X axis, Z axis and oblique axes therebetween in the horizontal plane 3. Selective limitation of rotational freedom at the curved bearing surface and/or selective
35 limitation of rotational or translational freedom at the planar bearing surface can be provided by configurational arrangements described below.

The curved articular surface of the end piece or intermediate piece can be concave or convex. If the curved articular surface of the intermediate piece is

concave, the cooperating articular surface of the end piece will be convex.

Alternatively, if the curved articular surface of the intermediate piece is convex, the cooperating articular surface of the end piece will be concave. As used herein, the term "curved" includes configurations such as cylindrical, ellipsoidal, spherical, oblong, etc. As will be discussed, each of these curved configurations affect the type and range of rotational movement which can occur between the vertebral bodies.

The perimeter edge of the linear articular surface of the end piece can be flush or have a protruding lip relative to the articular surface. The configuration of a raised perimeter edge of the end piece and the shape of the linear articular surface of the intermediate piece can be used to affect the freedom of translational or axial rotation at the linear bearing surface. In some embodiments, the raised perimeter edge of the end piece can also affect the rotational range of the curved bearing surface.

The non-bearing or contact surfaces of each of the end pieces can include spikes, porous ingrowth surfaces, contoured surfaces which coaptate with the anatomical surfaces of the vertebral end plate, knurled surfaces, biological surfaces, or other similar arrangement to facilitate anchoring the end piece to the end plate of the vertebral bodies. Alternatively, or additionally, the end pieces of the device can be anchored to the vertebral bodies using bone screws.

In general, the prosthetic devices of the invention are non-compressible. As used herein, "non-compressible" means that the overall height of the device does not change substantially when subjected to the axial forces of patient's body weight. Suitable materials for manufacturing a non-compressible device include metals such as titanium, titanium alloys, stainless steel, cobalt/chromium, etc.; plastics such as poly(ethylene) with ultra high molar mass (molecular weight) (UHMW-PE), polyether ester ketone (PEEK), etc.; ceramics; graphite; etc. The bearing surfaces or articular surfaces can be prepared from metals such as titanium, titanium alloy, stainless steel, cobalt/chromium; plastics such as UHMW-PE, PEEK, etc.; graphite; ceramic; etc. The materials for opposing articular surfaces are preferably selected to minimize the amount of seizing which may occur during movement of the articular surfaces against one another.

Because the devices are non-compressible, providing devices of varying height, measured from the contact surface of a first end piece to the contact surface of the second end piece, permits selecting a device of appropriate height to maintain a desired intervertebral spacing between the vertebrae. The overall height of the device can be varied by increasing or decreasing the thickness of one or more of the first end piece, second end piece and intermediate piece. In addition, in some embodiments, by varying the angulation between the contact surface and the

articular surface of one or both end pieces, the prosthetic device can provide a selected degree of lordosis between opposing vertebrae.

The prosthetic devices of the invention will be further described by reference to the following illustrated embodiments. The illustrated embodiments are not intended to limit the scope of the invention, but rather, are provided to facilitate understanding of the devices and methods within the principles of the invention.

Detailed Description of the Illustrated Embodiment

With reference to the several drawing figures in which identical elements are numbered identically throughout, a description of some embodiments of an intervertebral prosthetic device according to the present invention will now be provided.

FIG. 3 is a perspective view of one embodiment of an intervertebral prosthetic device (IPD) **10** according to the present invention. FIG. 4 is an exploded perspective view of the IPD **10** of FIG. 3 and FIG. 5 is a top plan view. While the perimeter shape of the illustrated IPD is circular, the external configuration of an IPD of the invention can be any shape including, for example, circular, rectangular, square, trapezoidal, oblong, square or trapezoidal with rounded corners, elliptical, kidney bean shaped, etc. FIGs. 3a-5a illustrate an elliptical shaped IPD, the components are identified by the same reference numbers as the device of FIGs. 3-5 but are preceded by the letter "a."

The IPD **10** includes a first end piece **20** a second end piece **21** and an intermediate piece **22**. The IPD **10** can be inserted into an intervertebral disc space between an adjacent cranial and caudal vertebrae such that end piece **20** contacts the cranial vertebrae and end piece **21** contacts the caudal vertebrae. Alternatively, the IPD **10** can be inserted in the intervertebral disc space with second end piece **21** in contact with the cranial vertebrae and first end piece **20** in contact with the caudal vertebrae.

FIG. 6 is a cross-section view taken through the IPD **10** of FIG. 5 at line 6-6. FIG. 7 is a cross-section view taken through line 7-7. If inserted in an intervertebral space of a patient, FIG. 7 would be a left lateral view.

As seen in FIGs. 6 and 7, the first end piece **20** includes a first end base **23** having a first end contact surface **24** and a first end articular surface **25**. Similarly, second end piece **21** includes a second end base **26** having a second end contact surface **27** and a second end articular surface **28**. In FIGs. 3-7, the contact surfaces **24** and **27** include an anchoring arrangement **29** for fixing the end piece to the end plates of a vertebral body. The illustrated anchoring arrangement **29** includes spikes **30** which can be embedded into the vertebral end plates to anchor

device **10** to the vertebrae. Alternative anchoring arrangements **29** at contact surfaces **24** and **27** include porous coated ingrowth surfaces, knurled surfaces, contoured or textured surfaces, biological coatings (e.g., peptide coatings, etc.), etc. Bone cement, osteoconductive materials, osteoinductive materials, and other known systems can also be used to facilitate anchoring an IPD to the end plates of adjacent vertebrae. In addition, as discussed below, bone screws can be used to fix the end pieces to the vertebrae.

In the embodiment of FIGs. 3-7, the first end articular surface **25** is a convex curved surface **31**. The second end articular surface **28** is a planar surface **35**. A raised edge **100** is provided around the perimeter of second end articular surface **28**. As best seen in FIGs. 6 and 7, first end articular surface **31** can be spherical **32**. As best appreciated in FIG. 7, although the first end piece **20** and first end articular surface **31** both have circular perimeters, the central axis E_A of the first end piece **20** need not be coaxial with the central axis S_A of the first end piece articular surface **31**.

The intermediate piece **22** includes an intermediate base **45**, a first intermediate articular surface **46** and second intermediate articular surface **47**. The first intermediate articular surface **46** is a concave curve **48** and the second intermediate articular surface **47** is planar **49**. As stated above, in alternative embodiments, the concave curved surface can be a part of the end piece and the convex curved surface can be a part of the intermediate piece.

Thus, when components **20**, **21**, **22** are assembled, the first intermediate articular surface **46** cooperatively articulates with first end articular surface **25** forming first assembly bearing surface **50**. The second intermediate articular surface **47** cooperatively articulates with second end articular surface **28** forming second assembly bearing surface **51**. In the illustrated embodiment, the first assembly bearing surface **50** is curved and the second assembly bearing surface **51** is planar.

The curved assembly bearing surface **50** allows at least three degrees of rotational freedom unconstrained throughout the anatomical range of motion between the vertebral bodies. The second assembly bearing surface **51** allows at least two degrees of translational freedom and one degree of rotational freedom. That is, curved assembly bearing surface **50** provides for anterior/posterior rotation (flexion/extension) in a sagittal plane **1** (see FIG. 1), lateral rotation (lateral bending) in a frontal plane **2** and axial rotation along the Y axis. Rotational motion can also occur in planes oblique to the sagittal **1** and frontal **2** planes. Planar assembly bearing surface **51** provides translational motion in horizontal plane **3** along the Z

axis and X axis and rotational motion about the Y axis. Translational motion can also occur along axes oblique to the X and Z axes in the horizontal plane 3.

Referring now to FIGs. 8-10, the variable instantaneous axis of rotation provided by an IPD of the invention during vertebral movement will be described. FIGs. 8-10 are sagittal cross-section views taken through 7-7 of FIG. 5, viewed from the patient's left side. In FIG. 8, the IPD 10 is shown when the patient is in the neutral or standing position. The instantaneous axis of rotation (IAR) at this position is at line 112. In FIG. 9, during extension (posterior rotation), the IAR shifts posteriorly to position 113. In FIG. 10, during flexion (anterior rotation), the IAR shifts anteriorly to position 114. Thus, the translational freedom provided by flat bearing surface 51 readily permits the IAR to shift as dictated by the change in the relative positions of the adjacent vertebrae. This translational freedom provides a variable instantaneous axis of rotation. In addition to the anterior/posterior translational freedom illustrated in FIGs. 8-10, flat bearing surface 51 also permits translational freedom in a lateral direction as well as in any other direction within horizontal plane 3 of FIG. 1. As will be discussed below, limiting arrangements such as raised edge 100 can be configured to limit the rotational or translational freedom provided at the planar bearing surface 51. Before addressing limitations to rotational freedom, however, configurations for limiting certain rotational freedoms will be discussed.

FIG. 11 is a top view of intermediate piece 22 of FIG. 3 and FIG. 12 is a cross-section view of FIG. 11. The concave curve 48 of first intermediate articular surface 46 is spherical 32. This concave spherical surface 32 permits a convex articular surface 25 of first end piece 20 to rotate freely in a sagittal plane, frontal plane or around the Y axis.

In an alternative embodiment of an intermediate piece 150 illustrated in FIGs. 13-15, the concave surface 151 is ellipsoidal 152. The longitudinal cross-section of FIG. 14 is taken through line 14-14 of FIG. 13 and the transverse cross-section of FIG. 15 is taken through line 15-15. When intermediate piece 150 is oriented within an IPD with long dimensions 14-14 parallel to the frontal plane 2, the ellipsoidal surface 152 will permit substantially full anterior/posterior rotation, but lateral rotation will be limited. If long dimension 14-14 is oriented parallel to sagittal plane 1, lateral rotation will be substantially free and anterior posterior rotation limited. According to this embodiment, the cooperating articular surface is preferably also ellipsoidal.

FIGs. 16-18 show another embodiment of an intermediate piece which limits rotational motion to a single plane at the curved bearing surface 50. As seen in top view of FIG. 16, intermediate piece 175, has a curved bearing surface

176 which is cylindrical 177. FIG. 17 is a long dimension cross-section taken through line 17-17 of FIG. 16 and FIG. 18 is a transverse cross-section view taken through line 18-18 of FIG. 16. This configuration limits lateral rotation when long dimension 17-17 is oriented parallel to the frontal plane 2 and limits
5 anterior/posterior rotation when long dimension 17-17 is oriented parallel to the sagittal plane 1.

FIG. 19 is a cross-section view through an alternative embodiment of an IPD 200 showing an alternative limiting arrangement 201 for limiting rotation of curved bearing surface 203. According to this embodiment, a raised lip 204 is
10 present around the perimeter edge 205 of planar articular surface 206. In addition, a raised lip 207 is also present at the perimeter edge 212 surrounding curved articular surface 213. Thus, in the embodiment of FIG. 19, lip 204 not only limits translational motion at the perimeter edge 201 of the planar articular surface 206, but also, rotation of curved articular surface 213 is limited when lip 204 meets lip 207.
15 In addition, rotation at curved bearing surface 215 is also limited when flange 217 of intermediate piece 218 contacts flat perimeter surface 219 surrounding curved articular surface 213. Similar limiting effects can be obtained by positioning one or more raised stops in place of the illustrated lip.

Translational freedom of an IPD can also be limited at the flat bearing
20 surface. Referring to FIGs. 20-24, in one embodiment, raised perimeter edge 250 of end piece 260 can be configured such that the edge 250 forms a track 251 around flat articular surface 252 as illustrated in the top plan view of FIG. 20. FIG. 21 is a bottom plan view of an intermediate piece 270 having a peg 271, best illustrated in the bottom perspective view of FIG. 22. In this embodiment, translational rotation is
25 limited to one degree as peg 271 travels in track 251 of end piece 260. The short sides 261 at the ends of long dimension 23-23 of track 251 do not need to be present to limit the translational freedom described for this embodiment.

FIG. 23 is a cross-section through the long dimension 23-23 of track 251 when intermediate piece 270 is in cooperating relationship with end piece 250.
30 FIG. 24 is a transverse cross-section through line 24-24 of the same cooperative arrangement as FIG. 23. Rotational freedom at the flat articular surface is not limited. As illustrated in FIGs. 23 and 24, in this embodiment, the flat bearing surface 51 includes articulating surfaces 272 and 273 at two levels.

Referring to the embodiment of intermediate piece 280 in FIGs. 25
35 and 26, when intermediate piece 280 is in cooperative arrangement with end piece 250, the linear edges 281 of peg 282 are guided by the edges of track 251 to limit axial rotation in addition to limiting one degree of translational freedom.

In yet another embodiment, FIG. 27 illustrates an intermediate piece **300** substantially similar to intermediate piece **270** of FIG. 21. However, as illustrated in FIG. 28, in this embodiment the diameter of peg **301** is less than the width of track **251** of end piece **260**. Thus, when intermediate piece **300** and end piece **260** are in cooperating arrangement, intermediate piece **300** has the same translational freedom as intermediate piece **270** in long dimension 23-23, but, due to the smaller diameter of peg **301**, intermediate piece **300** has an increased lateral translational freedom.

Various configurations of "tracks" and "pegs" will be apparent which are within the scope of the invention and which can be combined to provide a particular type of limitation to motion. For example, the elliptically shaped perimeter of an intermediate piece **22a**, such as illustrated in FIG. 4a, can be cooperatively arranged with an appropriately sized track, such as an oblong track **265** of FIG. 20 to provide substantially full translational freedom along long dimension 23-23 and some degree of rotational freedom due to the narrowing at the long dimension ends of an elliptical intermediate piece **22a**. Increased lateral freedom can also be provided by making the short dimension of elliptical intermediate piece **22a** less than the short dimension through line 24-24 of oblong track **265**.

Referring to FIG. 29, it will be appreciated that an IPD such as IPD **10** has an overall height dimension H extending from first end contact surface **24** to second end contact surface **27**. The height dimension H can be varied by varying one or more of the height dimensions of first end base **23** (H_1), intermediate base **45** (H_3) or second end base **26** (H_2). By providing IPDs **10** having various height dimensions H , an IPD **10** of selected height can be used for a desired intervertebral spacing between adjacent vertebrae.

FIGs. 30 and 31 are cross-section views of two alternative embodiments of an IPD for creating a selected degree of lordosis between adjacent vertebrae. IPD **300** of FIG. 30 includes a first end piece **301** having a taper to provide the desired degree of lordosis. In this embodiment, second end piece **302** does not include a taper. The taper of first end piece **301** from edge **303** to edge **304** can be approximately $0-22^\circ$. Referring to the IPD **350** of FIG. 31, both first end piece **351** and second end piece **352** have a taper from edge **353** to edge **354**. The combined IPD taper from edge **353** to edge **354** can be about $0-22^\circ$.

FIGs. 32 and 33 illustrate IPDs **400** and **420** having two different anchoring arrangements **29** which can be used alone, in combination with one another, or in combination with other anchoring arrangements. In FIG. 32, anchoring arrangement **29** comprises an anchoring tab **401** having bores **402** through

which lag screws can be passed into the anterior surface of the vertebrae. In FIG. 33, end pieces 410 and 411 each have bores 412 through which lag screws can be passed to anchor the IPD to the end plates of the vertebrae.

5 Generally, the materials of an IPD are non-compressible. That is, the materials render the IPD substantially resistant to axial compression by the weight of the patient into which the device is inserted. Examples of suitable materials were described above. Combinations of materials can also be used in a single IPD. For example, in one embodiment, an IPD can include a first end piece and second end piece manufactured from titanium and an intermediate piece manufactured from
10 UHMW-PE, PEEK, or other suitable plastic. In an alternative embodiment, an IPD can include a first and second end piece manufactured from cobalt/chromium with an intermediate piece manufactured from UHMW-PE, PEEK or other plastic. In yet another alternative, each of the first end piece, second piece and intermediate piece can be manufactured from cobalt/chromium.

15 Known methods for insertion of intervertebral prosthetic devices can be used for insertion of an IPD according to the invention. Typically, the surgical procedure for insertion of an IPD into the intervertebral disc space will be performed through an anterior, lateral or anterior-lateral approach.

20 From the foregoing detailed description and examples, it will be evident that modifications and variations can be made in the devices and methods of the invention without departing from the spirit or scope of the invention. Therefore, it is intended that all modifications and verifications not departing from the spirit of the invention come within the scope of the claims and their equivalents.

WE CLAIM:

1. An intervertebral disc prosthesis for placement between first and second adjacent vertebrae, comprising:
 - 5 - a first end member for contacting the first vertebra, said first end member having a first flat surface;
 - a second end member for contacting the second vertebra, said second end member having a first curved surface;
 - 10 - an intermediate member having an intermediate flat surface and an intermediate curved surface such that said intermediate flat surface coaptates with said first flat surface and said intermediate curved surface coaptates with said first curved surface.
- 15 2. The intervertebral disc prosthesis according to claim 1 wherein said first curved surface is concave and said intermediate curved surface is convex.
3. The intervertebral disc prosthesis according to claim 1 wherein said first curved surface is convex and said intermediate curved surface is concave.
- 20 4. The intervertebral disc prosthesis according to claim 1 wherein said intermediate curved surface is spherical.
5. The intervertebral disc prosthesis according to claim 1 wherein said intermediate curved surface is ellipsoidal.
- 25 6. The intervertebral disc prosthesis according to claim 1 wherein when inserted between the adjacent vertebrae said ellipsoidal surface has a long axis which is parallel to a frontal plane.
- 30 7. The intervertebral disc prosthesis according to claim 1 wherein said intermediate curved surface is cylindrical.
8. The intervertebral disc prosthesis according to claim 1 wherein said first flat surface includes a raised perimeter edge.
- 35 9. The intervertebral disc prosthesis according to claim 1 wherein said first and second end members each include a first and second contact surface,

respectively, each of said contact surfaces having an anchoring arrangement for attaching said prosthesis to the vertebrae.

- 5 10. The intervertebral disc prosthesis according to claim 9 wherein said anchoring arrangement includes at least one spike.
11. The intervertebral disc prosthesis according to claim 1 wherein said prosthesis includes bores for passing screws for anchoring said prosthesis to said first and second vertebrae.
- 10 12. The intervertebral disc prosthesis according to claim 1 wherein said prosthesis includes cobalt/chromium.
13. The intervertebral disc prosthesis according to claim 1 wherein said prosthesis includes plastic.
- 15 14. The intervertebral disc prosthesis according to claim 1 wherein said prosthesis includes ceramic.
- 20 15. The intervertebral disc prosthesis according to claim 1 wherein said prosthesis includes graphite.
16. The intervertebral disc prosthesis according to claim 1 wherein said first flat surface, first curved surface, intermediate flat surface and intermediate curved surface include cobalt/chromium.
- 25 17. An intervertebral prosthetic device for placement between first and second adjacent vertebrae, comprising:
 - 30 - a first end piece for engaging said first vertebra;
 - a second end piece for engaging said second vertebra; and
 - a center piece which fits between said first and second end pieces, said center piece providing a variable instantaneous axis of rotation.
18. The intervertebral prosthesis device according to claim 17 wherein said center piece includes a curved surface and a flat surface.
- 35 19. The intervertebral prosthesis device according to claim 18 wherein said curved surface is spherical.

20. The intervertebral prosthesis device according to claim 18 wherein said curved surface is ellipsoidal.
21. The intervertebral prosthesis device according to claim 18 wherein said curved surface and flat surface includes cobalt/chromium.
22. An intervertebral prosthetic device for placement between first and second adjacent vertebrae, comprising:
- a first end piece for engaging said first vertebra;
 - a second end piece for engaging said second vertebra; and
 - a center piece which fits between said first and second end pieces, said center piece providing linear translational freedom during vertebral rotation.
23. The intervertebral prosthetic device according to claim 22 having at least two degrees of linear translational freedom.
24. The intervertebral prosthetic device according to claim 22 wherein said device provides at least three degrees of rotational freedom and at least two degrees of translational freedom.
25. The intervertebral prosthetic device according to claim 22 wherein said first end piece includes a flat surface.
26. The intervertebral prosthetic device according to claim 25 wherein said flat surface includes a raised perimeter edge.
27. The intervertebral prosthetic device according to claim 26 wherein said raised perimeter edge forms an oblong track which substantially limits translational freedom in at least one direction.
28. A non-compressible intervertebral disc device for placement between first and second adjacent vertebrae, comprising:
- a first bearing surface providing at least one degree of rotational freedom;
 - a second bearing surface providing at least one degree of linear translational freedom.

29. The intervertebral disc device according to claim 28 wherein said first bearing surface provides at least three degrees of rotational freedom and said second bearing surface also provides one degree of rotational freedom.
- 5 30. The intervertebral disc device according to claim 28 wherein said second bearing surface provides at least two degrees of linear translational freedom.
31. A non-compressible intervertebral disc device for placement between first and second adjacent vertebrae, comprising:
- 10 - a first bearing surface, a second bearing surface and a variable instantaneous axis of rotation.
32. The non-compressible intervertebral disc device according to claim 31 wherein said first bearing surface provides at least one degree of rotational freedom and said second bearing surface provides at least one degree of translational freedom.
- 15 33. The non-compressible intervertebral disc device according to claim 32 wherein said first bearing surface is curved.
- 20 34. A method for providing intervertebral mobility between adjacent first and second vertebrae comprising a step of:
- inserting into an intervertebral space between said adjacent first and second vertebrae a non-compressible prosthetic device which provides a variable instantaneous axis of rotation.
- 25 35. A method for providing intervertebral mobility between adjacent first and second vertebrae comprising a step of:
- inserting into an intervertebral space between said adjacent first and second vertebrae a non-compressible prosthetic device which provides translational mobility between said adjacent vertebrae during rotation.
- 30 36. A method for providing intervertebral mobility between adjacent first and second vertebrae comprising a step of:
- inserting into an intervertebral space between said adjacent first and second vertebrae a prosthetic device having a first bearing surface and a second bearing surface wherein said second bearing surface
- 35

includes two articulating surfaces which can each independently move in a linear plane.

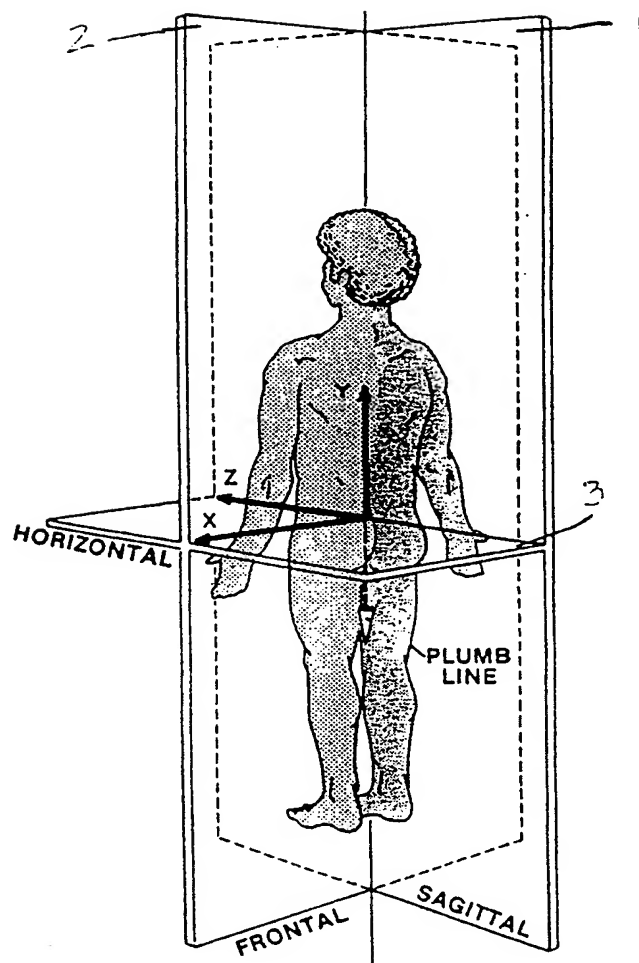
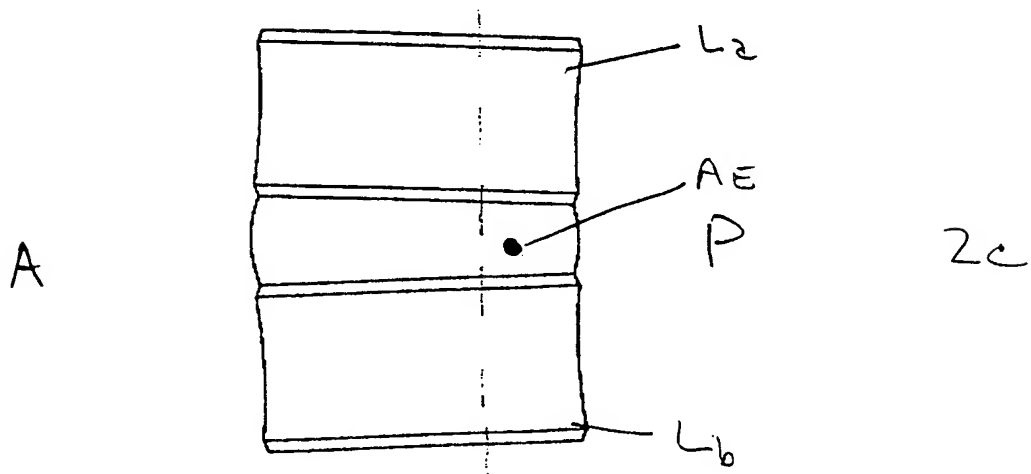
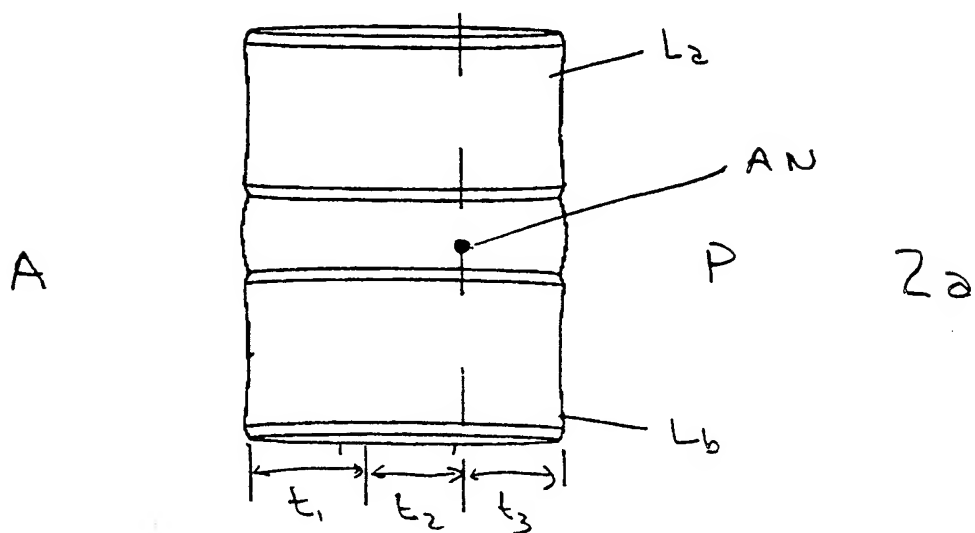
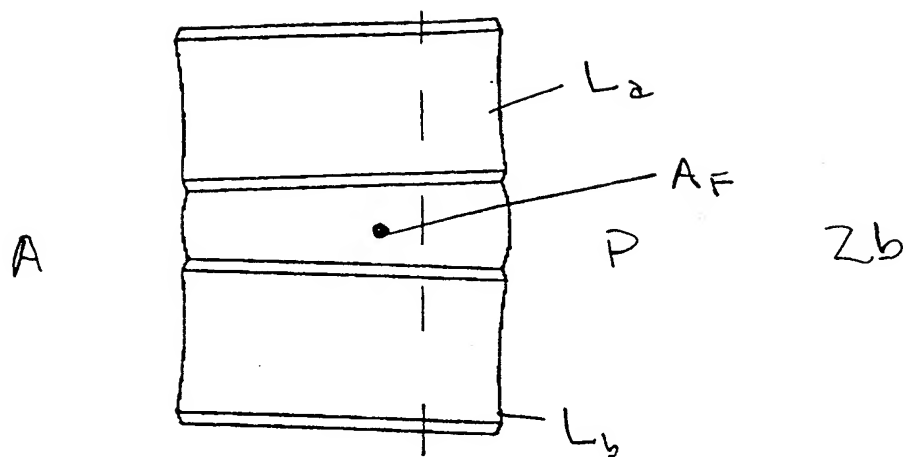
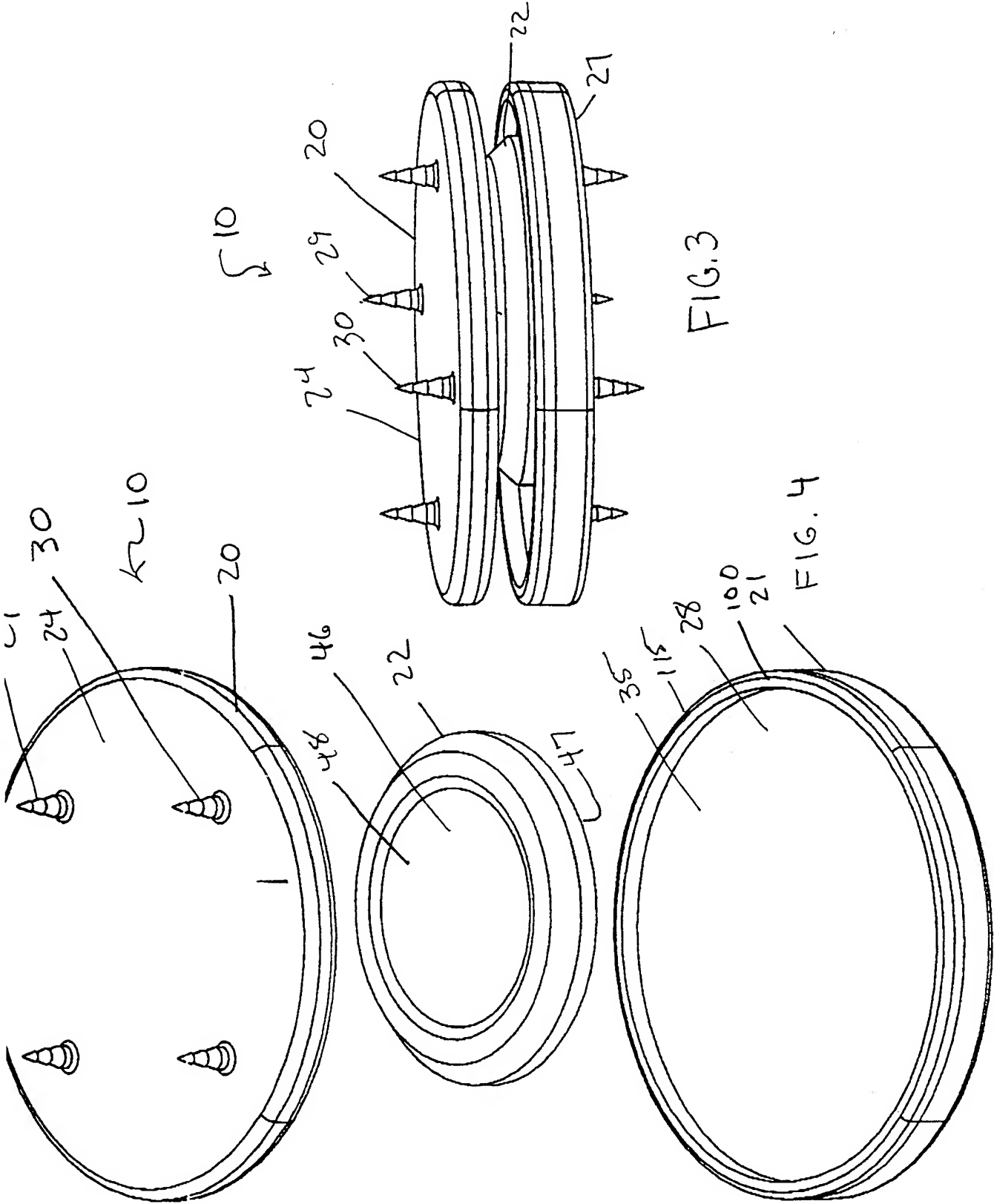
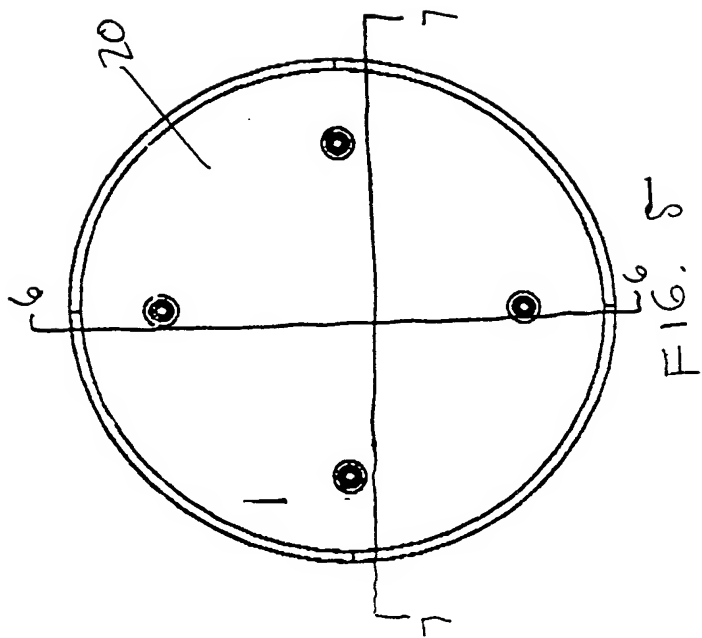
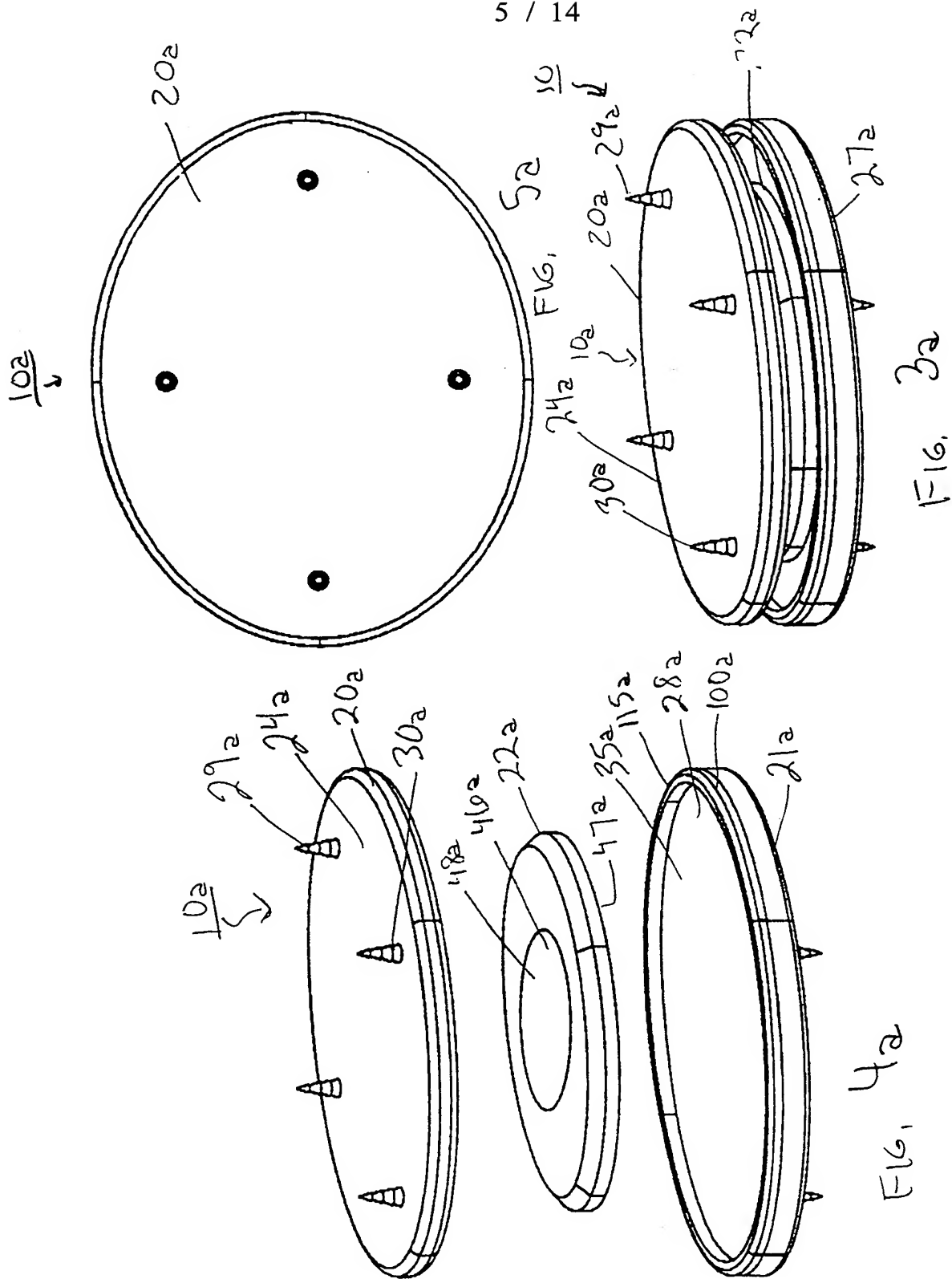


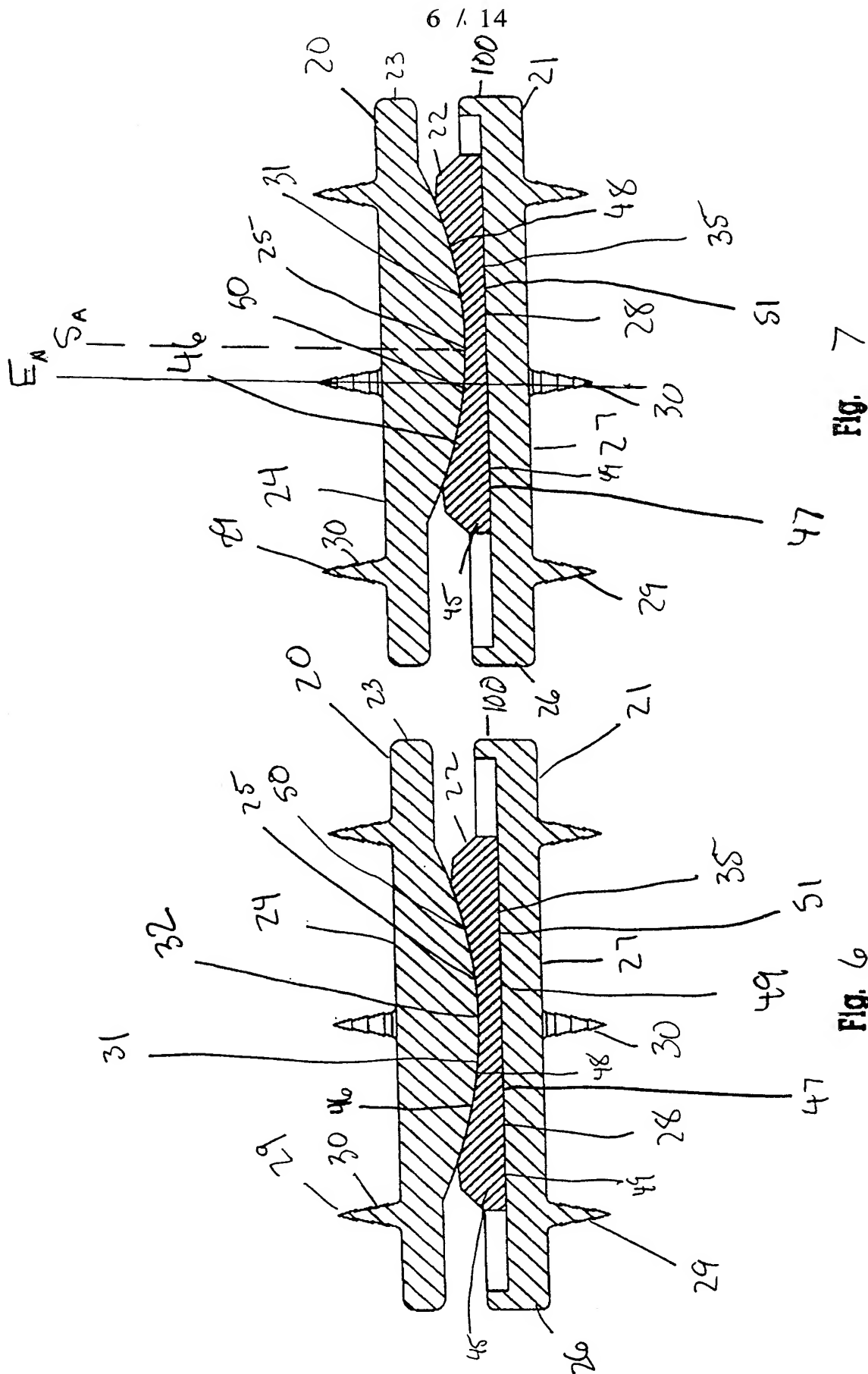
FIG. 1

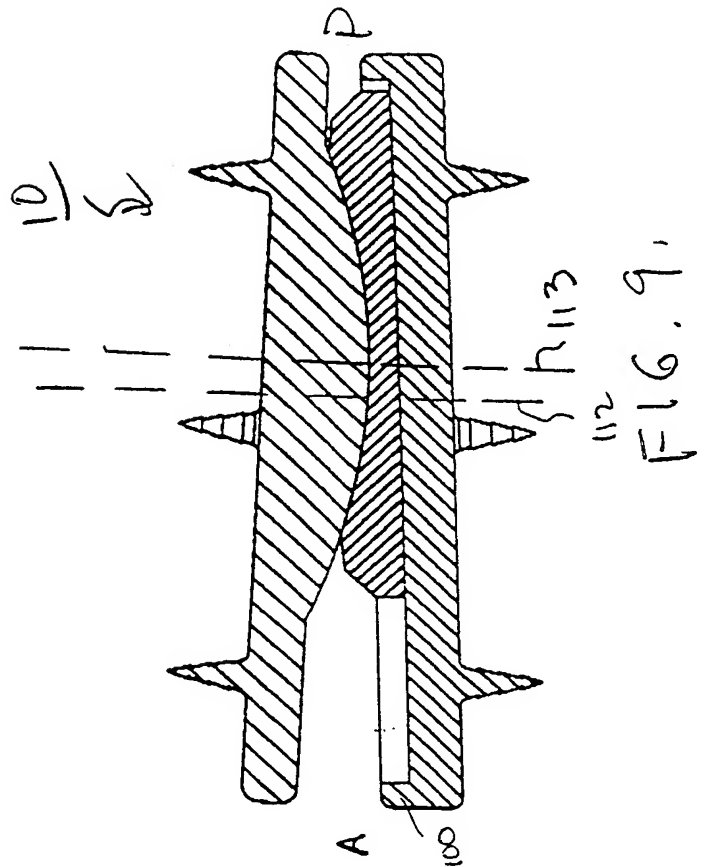
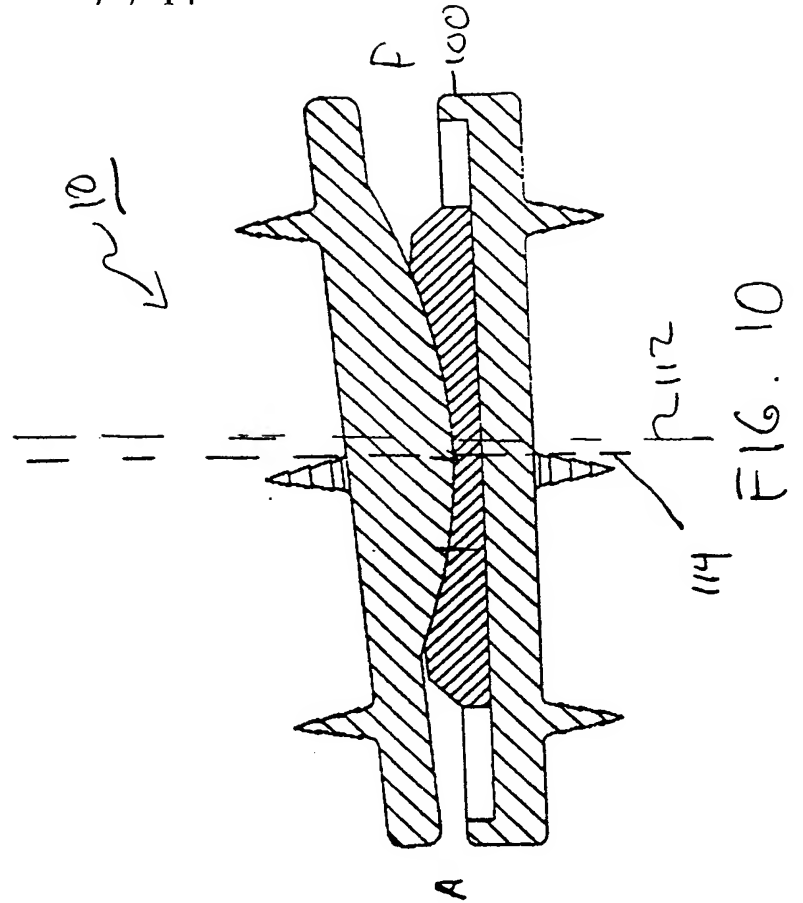
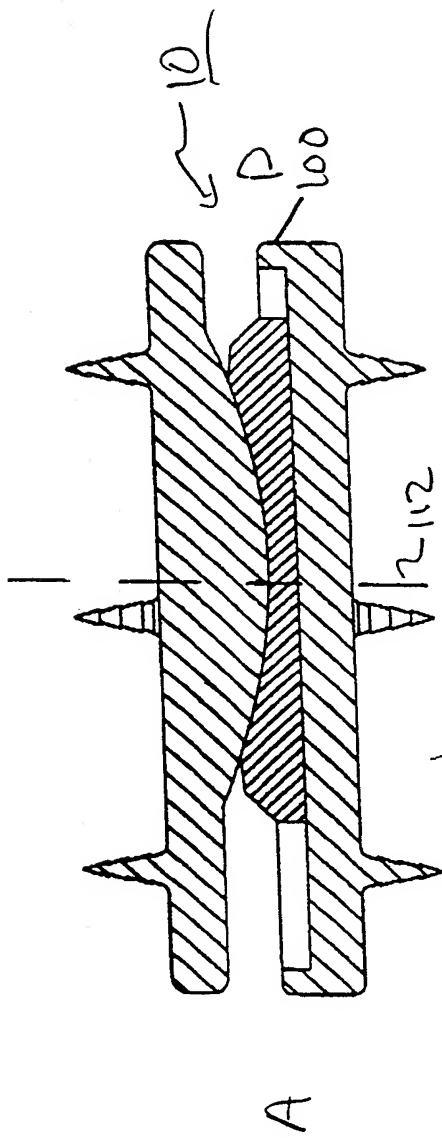


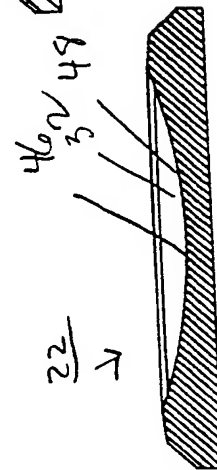
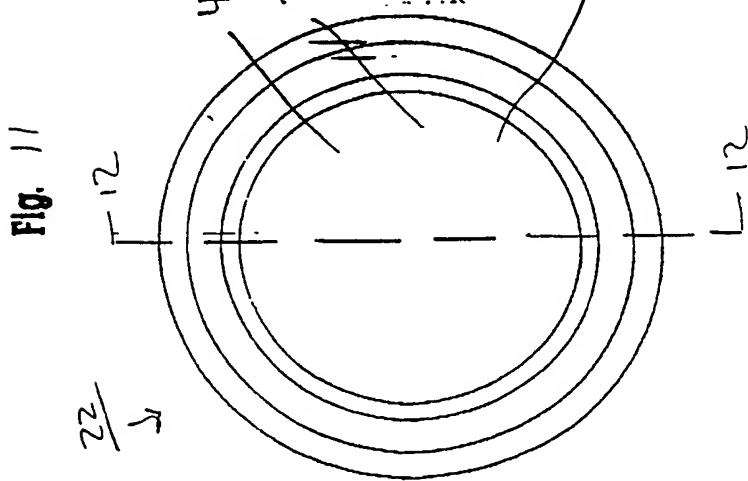
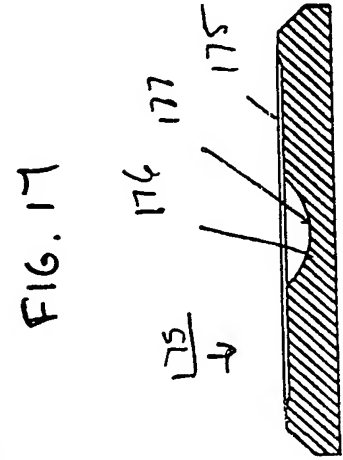
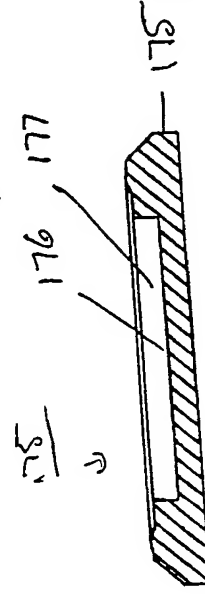
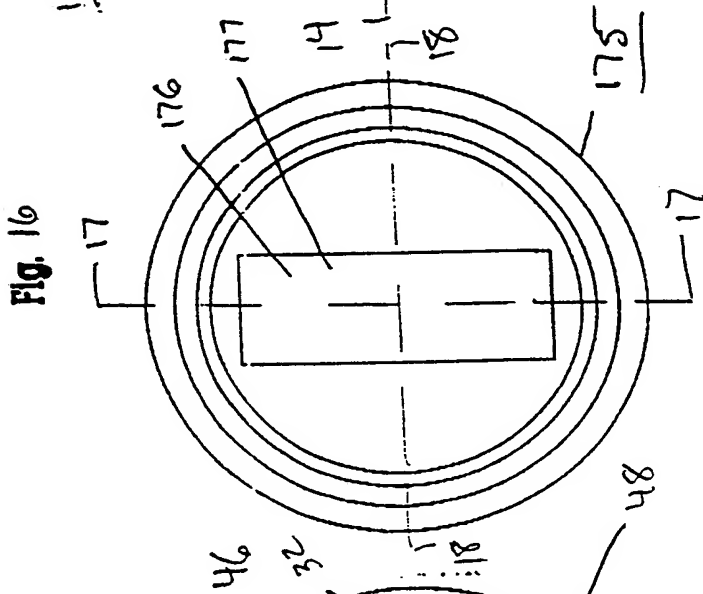
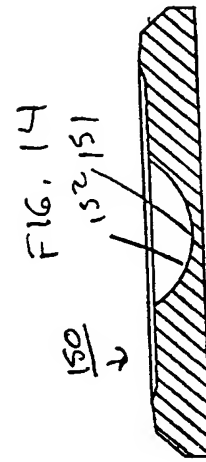
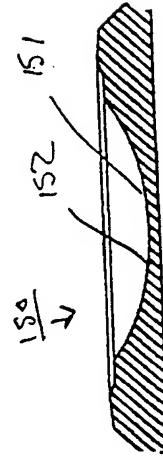
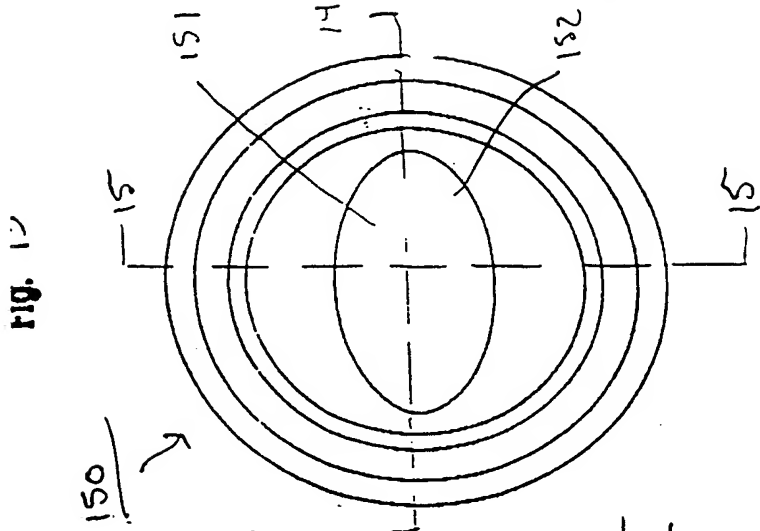












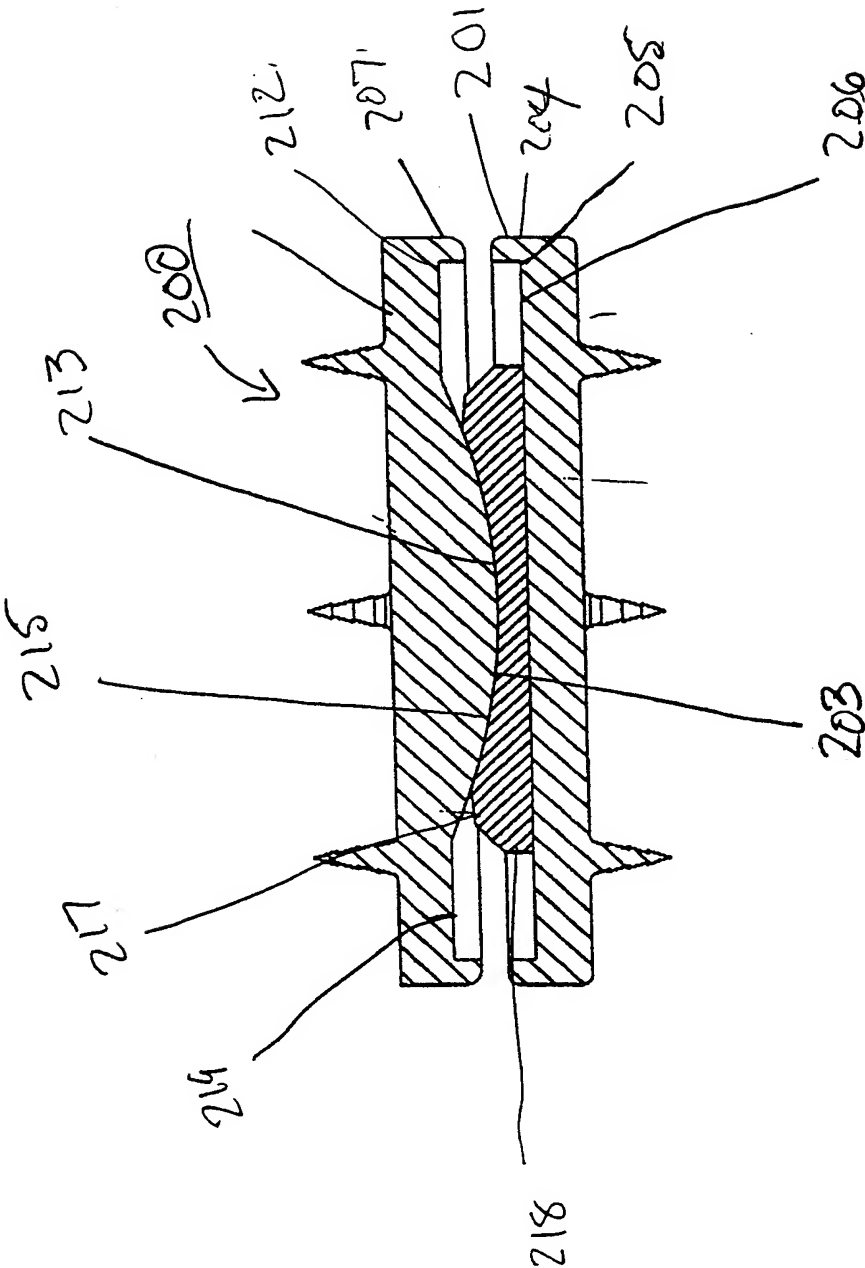


Fig. 19

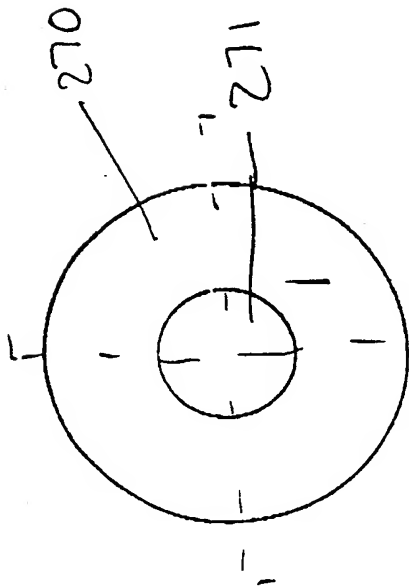
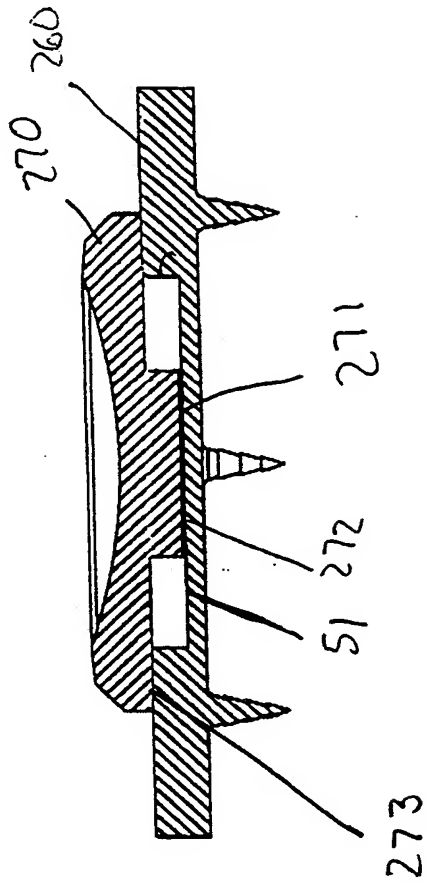


Fig. 21



Fig's. 23

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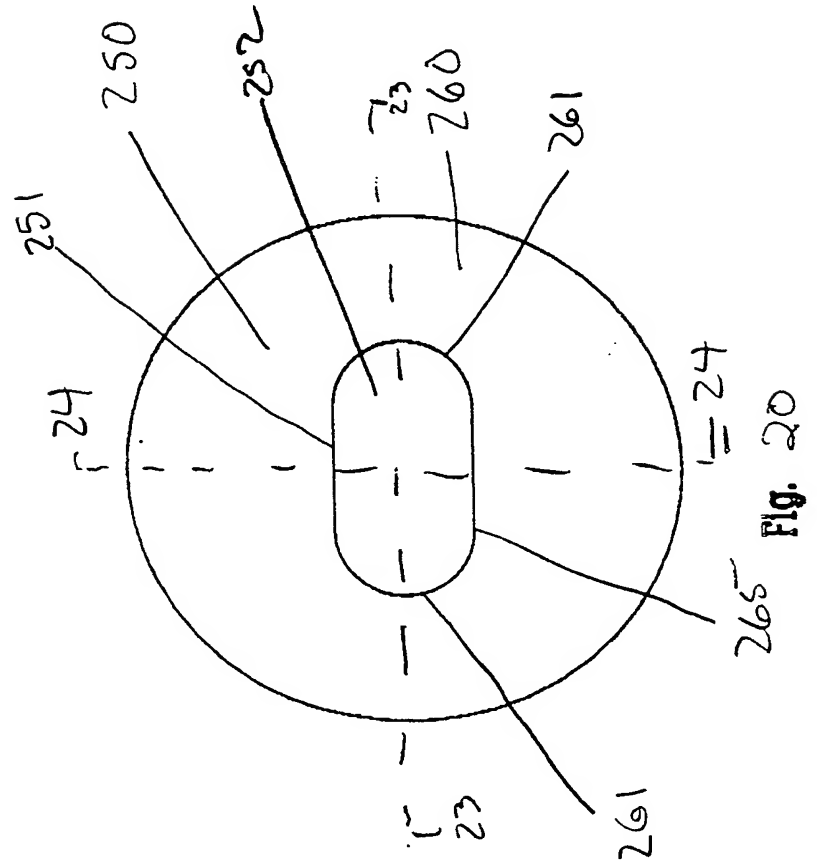
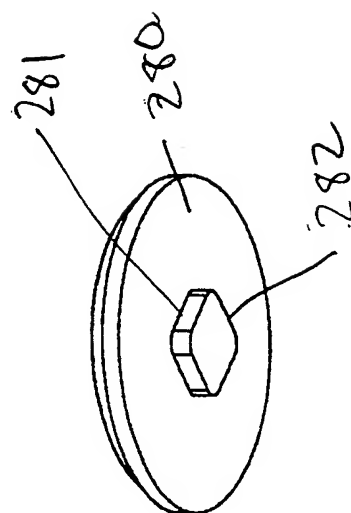
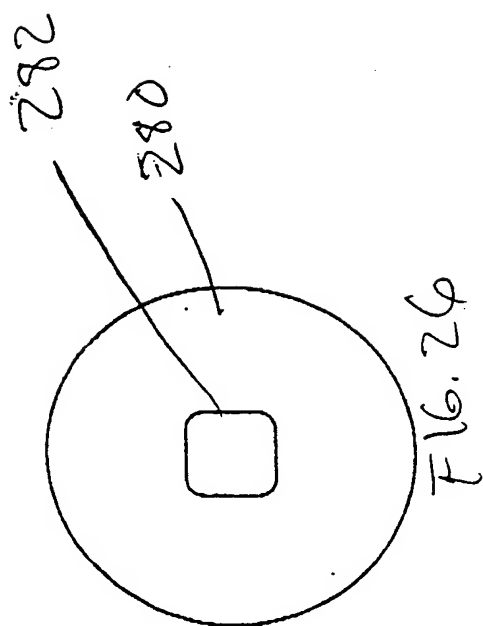


Fig. 20



FIGS. 25

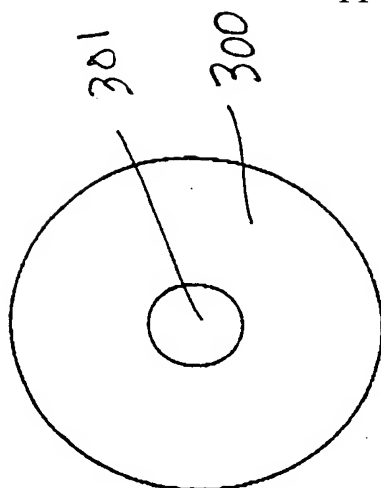
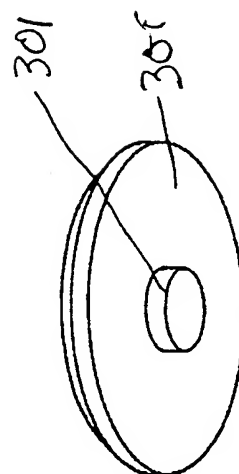
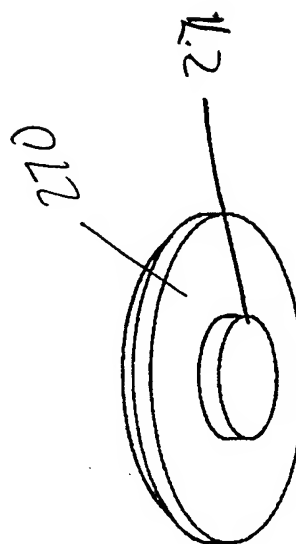


FIG. 26



FIGS. 27



FIGS. 28

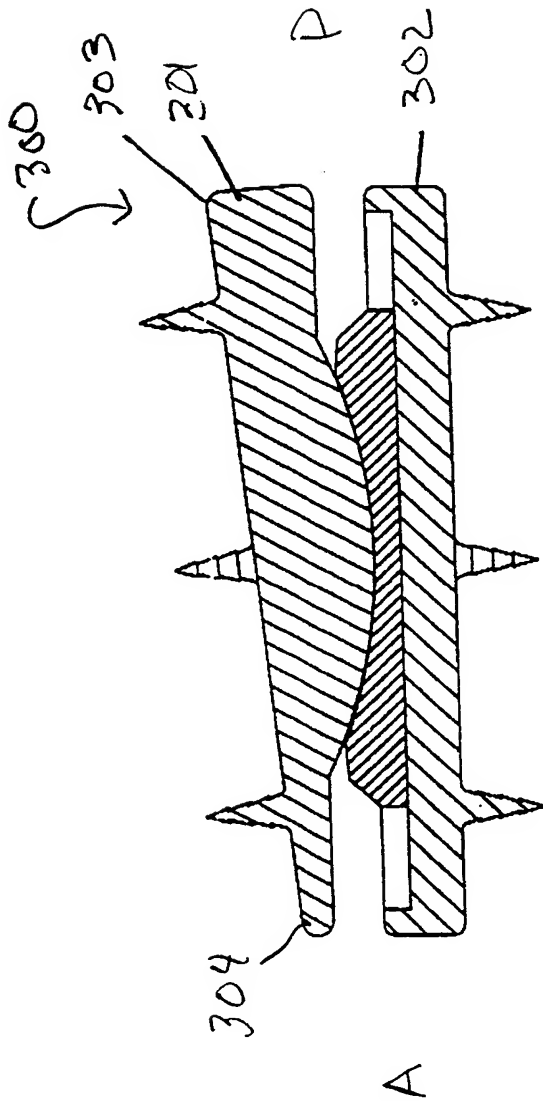


Fig. 30

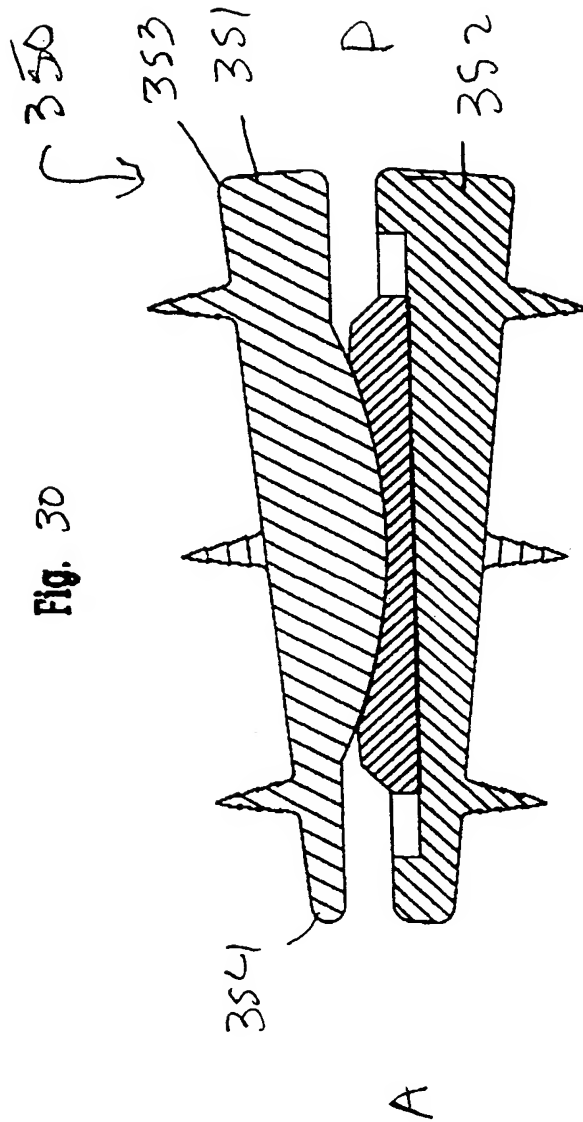
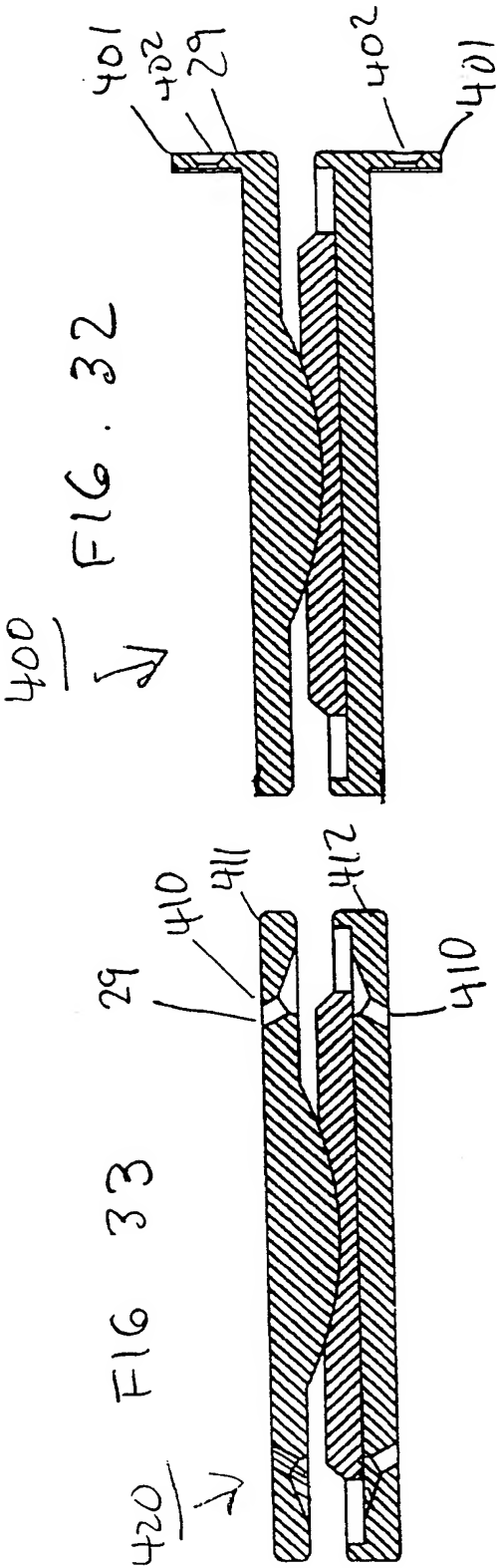


Fig. 31



INTERNATIONAL SEARCH REPORT

Internal Application No

PCT/US 00/06172

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 425 773 A (PETTINE KENNETH A ET AL) 20 June 1995 (1995-06-20) figures 2-10 column 4, line 45 -column 6, line 19 column 6, line 27 -column 7, line 2 column 7, line 10 - line 40 claims 1-7	1,2,4-6, 9-21,31
A	--- -/--	22,28

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

10 July 2000

Date of mailing of the international search report

17/07/2000

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/06172

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 730 159 A (TEULE JEAN GERMAIN) 9 August 1996 (1996-08-09) figures 1-6 page 4, line 25 -page 6, line 2 page 6, line 11 -page 9, line 20 page 11, line 14 - line 17 claims 1-11 ----	1-6, 8-10, 13, 17-20, 22, 25-28, 31-33
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International Application No

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(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES
PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro



(43) Internationales Veröffentlichungsdatum
11. Januar 2001 (11.01.2001)

PCT

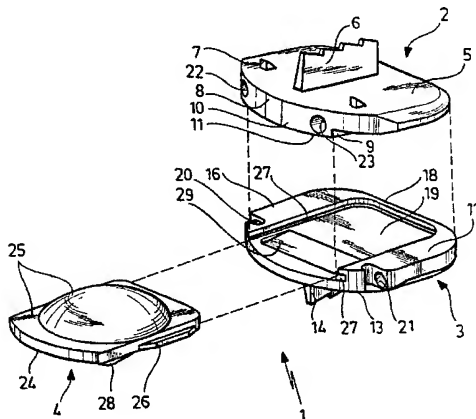
(10) Internationale Veröffentlichungsnummer
WO 01/01893 A1

- (51) Internationale Patentklassifikation⁷: A61F 2/44 (72) Erfinder; und
(21) Internationales Aktenzeichen: PCT/EP99/04628 (75) Erfinder/Anmelder (nur für US): MARNAY, Thierry [FR/FR]; 290, avenue Valéry Larbaud, F-34080 Montpellier (FR). BEYERSDORFF, Boris [DE/DE]; Möhringerstrasse 5, D-78532 Tuttlingen (DE).
(22) Internationales Anmeldedatum: 2. Juli 1999 (02.07.1999)
(25) Einreichungssprache: Deutsch (74) Anwalt: BÖHME, Ulrich; Hoeger, Stellrecht & Partner Patentanwälte GbR, Uhlandstrasse 14c, D-70182 Stuttgart (DE).
(26) Veröffentlichungssprache: Deutsch
(71) Anmelder (für alle Bestimmungsstaaten mit Ausnahme von US): SPINE SOLUTIONS INC. [US/US]; 505 Park Ave., 14th floor, New York, NY 10022 (US). (81) Bestimmungsstaaten (national): AE, AU, BR, CA, CZ, HR, HU, ID, IL, JP, KP, KR, MX, NZ, PL, RO, RU, SG, TR, US, YU, ZA.

[Fortsetzung auf der nächsten Seite]

(54) Title: INTERVERTEBRAL IMPLANT

(54) Bezeichnung: ZWISCHENWIRBELIMPLANTAT



(57) Abstract: The invention relates to an intervertebral implant (1), comprising an upper part (2) that has a support surface (5) for a vertebral body, and a lower part (3) that has a support surface (13) for an adjacent vertebral body. Contact elements (20, 21, 22, 23) are positioned on said upper part and said lower part and can be accessed from one side of the implant respectively, with an handling instrument. The aim of the invention is to minimize the structural height of the intervertebral implant (1) for insertion into an intervertebral space. To this end, the upper part (2) and the lower part (3) each have projections or recessed sections (9, 10, 16, 17, 19) which are oriented towards the other part and are laterally offset from each other in such a way that they engage in each other as the upper part (2) approaches the lower part (3). The contact elements (20, 21, 22, 23) are arranged on the upper part (2) and on the lower part (3) in projections (10, 16, 17) of these parts respectively, and the contact elements (20, 21, 22, 23) of the upper part (2) and the lower part (3) lie adjacent to one another and at least partially overlap in the direction of the height of the intervertebral implant (1).

(57) Zusammenfassung: Um bei einem Zwischenwirbelimplantat (1) mit einem eine Stützfläche (5) für einen Wirbelkörper aufweisenden Oberteil (2) und einem eine Stützfläche (13) für einen benachbarten Wirbelkörper aufweisenden Unterteil (3), an denen jeweils von einer Seite des Zwischenwirbelimplantats her zugängliche Angriffselemente (20, 21, 22, 23) für ein Handhabungsinstrument angeordnet sind, die Bauhöhe des Zwischenwirbelimplantats (1) beim

[Fortsetzung auf der nächsten Seite]

WO 01/01893 A1



(84) **Bestimmungsstaaten** (*regional*): eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Zur Erklärung der Zweibuchstaben-Codes, und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

Veröffentlicht:

— *Mit internationalem Recherchenbericht.*

Einführen in einen Zwischenwirbelraum zu minimieren, wird vorgeschlagen, dass Oberteil (2) und Unterteil (3) jeweils zum anderen Teil gerichtete Vor- bzw. Rückspünge (9, 10, 16, 17, 19) aufweisen, die seitlich so gegeneinander versetzt sind, dass sie bei an das Unterteil (3) angenähertem Oberteil (2) ineinander eingreifen, und dass die Angriffselemente (20, 21, 22, 23) am Oberteil (2) und am Unterteil (3) jeweils in Vorsprüngen (10, 16, 17) dieser Teile derart angeordnet sind, dass die Angriffselemente (20, 21, 22, 23) von Oberteil (2) und Unterteil (3) nebeneinander liegen und sich in Richtung der Höhe des Zwischenwirbelimplantats (1) zumindest teilweise überlappen.

- 1 -

ZWISCHENWIRBELIMPLANTAT

Die Erfindung betrifft ein Zwischenwirbelimplantat mit einem eine Stützfläche für einen Wirbelkörper aufweisenden Oberteil und einem eine Stützfläche für einen benachbarten Wirbelkörper aufweisenden Unterteil, an denen jeweils von einer Seite des Zwischenwirbelimplantats her zugängliche Angriffselemente für ein Handhabungsinstrument angeordnet sind.

Ein derartiges Zwischenwirbelimplantat ist beispielsweise aus der US-A-5,314,477 bekannt. Dieses Zwischenwirbelimplantat dient dem Ersetzen einer aus dem Zwischenwirbelraum entfernten Bandscheibe, und dementsprechend muß das Zwischenwirbelimplantat eine relativ geringe Bauhöhe aufweisen, da es in den Zwischenwirbelspalt hineinpassen muß. Dies ist insbesondere dann schwierig, wenn zwischen dem Oberteil und dem Unterteil noch ein zusätzlicher Gelenkeinsatz eingebettet ist, wie dies bei dem bekannten Zwischenwirbelimplantat der US-A-5,314,477 der Fall ist.

Schwierigkeiten ergeben sich aber auch schon bei zweiteiligen Zwischenwirbelimplantaten insbesondere dann, wenn diese an ihren Stützflächen noch Stifte und andere Vorsprünge tragen, die der Verankerung des Zwischenwirbelimplantates im Knochen dienen sollen. Diese können dann häufig nur dadurch eingesetzt werden, daß der Zwischenwirbelraum stark aufgeweitet wird. Dies ist nicht nur sehr schwierig, sondern birgt auch die Gefahr von Verletzungen in sich.

- 2 -

Da der Zwischenwirbelraum eine relativ geringe Höhe aufweist, ist es auch schwierig, an den beiden Teilen des Zwischenwirbelimplantates Angriffselemente zu befestigen, an denen ein Handhabungsinstrument angreifen kann. Es ist üblich, derartige Handhabungsinstrumente getrennt am Oberteil und am Unterteil angreifen zu lassen, beispielsweise durch Stifte, die in Bohrungen am Oberteil bzw. am Unterteil eingesteckt werden, so daß mit dem Handhabungsinstrument die beiden Teile des Zwischenwirbelimplantates in den Zwischenwirbelraum eingesetzt und gegebenenfalls auch in ihrem Abstand voneinander verändert werden können, so daß dadurch eine gewisse Aufspreizung des Zwischenwirbelraumes möglich ist. Hierzu wird beispielsweise verwiesen auf das zangenförmige Handhabungsinstrument in der US-A-5,314,477.

Aufgrund der großen Kräfte ist es notwendig, für die Angriffselemente eine gewisse Bauhöhe vorzusehen, beispielsweise müssen die Aufnahmebohrungen einen bestimmten Durchmesser aufweisen. Daraus ergibt sich eine minimale Bauhöhe für das Oberteil und für das Unterteil, und bei herkömmlichen Zwischenwirbelimplantaten addieren sich somit die Bauhöhen von Oberteil und Unterteil, so daß selbst beim unmittelbaren Aufeinanderliegen von Oberteil und Unterteil eine relativ große Bauhöhe des Zwischenwirbelimplantates unvermeidlich ist.

Es ist Aufgabe der Erfindung, ein gattungsgemäßes Zwischenwirbelimplantat so auszubilden, daß die minimale Bauhöhe herabgesetzt wird, um das Einführen des Zwischenwirbelimplantates in den Zwischenwirbelraum zu erleichtern.

- 3 -

Diese Aufgabe wird bei einem Zwischenwirbelimplantat der eingangs beschriebenen Art erfindungsgemäß dadurch gelöst, daß Oberteil und Unterteil jeweils zum anderen Teil gerichtete Vor- bzw. Rücksprünge aufweisen, die seitlich so gegeneinander versetzt sind, daß sie bei an das Unterteil angenähertem Oberteil ineinander eingreifen, und daß die Angriffselemente am Oberteil und am Unterteil jeweils in Vorsprüngen dieser Teile derart angeordnet sind, daß die Angriffselemente von Oberteil und Unterteil nebeneinander liegen und sich in Richtung der Höhe des Zwischenwirbelimplantats zumindest teilweise überlappen.

Bei einer solchen Ausgestaltung läßt sich eine minimale Bauhöhe der beiden aufeinanderliegenden Zwischenwirbelimplantatsteile erreichen, da die Angriffselemente, die eine minimale Bauhöhe nicht unterschreiten können, jeweils in Vorsprüngen von Oberteil bzw. Unterteil angeordnet sind, also in den Teilen mit der größten Bauhöhe von Oberteil und Unterteil. Diese Bereiche großer Bauhöhe sind als Vorsprünge ausgebildet, neben denen sich jeweils Rücksprünge befinden, in die die Vorsprünge des jeweils anderen Teils eintauchen können. Daraus ergibt sich einmal, daß die Angriffselemente für die Handhabungsinstrumente nebeneinander liegen, und zum anderen, daß diese sich zumindest teilweise überlappen können, so daß die Gesamtbauhöhe der aufeinanderliegenden Teile des Zwischenwirbelimplantates gegenüber herkömmlichen Zwischenwirbelimplantaten deutlich herabgesetzt werden kann. Es ergibt sich somit eine verschachtelte Anordnung von Oberteil und Unterteil mit maximaler Ausnutzung der zur Verfügung stehenden Materialhöhe.

- 4 -

Dabei ist es günstig, wenn die Angriffselemente Einstecköffnungen für stiftförmige Halteelemente eines Handhabungsinstrumentes sind, diese Einstecköffnungen können aufgrund der beschriebenen Konstruktion einen relativ großen Durchmesser aufweisen und damit kräftige Haltestifte aufnehmen, und trotzdem ergibt sich eine relativ geringe Bauhöhe des Zwischenwirbelimplantates bei unmittelbar aufeinandergelegten Teilen.

Dabei ist es vorteilhaft, wenn sich die Einstecköffnungen im wesentlichen parallel zu den Stützflächen erstrecken, auch dadurch wird vermieden, daß die Bauhöhe der Zwischenwirbelimplantatsteile vergrößert wird.

Bei einer bevorzugten Ausführungsform ist vorgesehen, daß das Unterteil eine der unteren Stützfläche gegenüberüberliegende zentrale Vertiefung aufweist, die von einem U-förmigen Rand umgeben ist. Die Vertiefung dient also bei unmittelbar aufeinanderliegendem Unterteil und Oberteil der Aufnahme eines Vorsprunges am Oberteil.

Dabei ist es vorteilhaft, wenn das Oberteil einen im wesentlichen komplementär in die Vertiefung passenden zentralen Vorsprung trägt, es wird also das gesamte Volumen der Vertiefung für den Vorsprung ausgenutzt.

Es ist weiterhin vorteilhaft, wenn die Angriffselemente des Unterteils an den beiden Enden des U-förmigen Randes angeordnet sind, also außen liegen.

Die Angriffselemente des Oberteils können dagegen an dem zentralen Vorsprung des Oberteils angeordnet sein,

- 5 -

liegen also gegenüber den Angriffselementen des Oberteils weiter innen.

Insbesondere können die Angriffselemente des Oberteils nahe der seitlichen Ränder des zentralen Vorsprungs angeordnet sein, so daß auch für das Oberteil der Abstand der Angriffselemente relativ groß gewählt werden kann, dadurch läßt sich das Oberteil ebenso wie das Unterteil gegen eine Verkipfung zuverlässig sichern.

Bereits hier sei darauf hingewiesen, daß die Ausdrücke "Unterteil" und "Oberteil" nicht unbedingt etwas über die Einbaulage des Zwischenwirbelimplantates in der Wirbelsäule aussagen, das mit "Unterteil" bezeichnete Teil könnte in der Wirbelsäule tatsächlich auch oben liegen. Wesentlich ist lediglich, daß Oberteil und Unterteil das Zwischenwirbelimplantat auf einander gegenüberliegenden Seiten des Implantates begrenzen.

Besonders vorteilhaft ist es, wenn das Oberteil und/oder das Unterteil im wesentlichen plattenförmig ausgebildet sind, wobei diese Teile natürlich entsprechend der erfindungsgemäßen Ausgestaltung Vor- und Rücksprünge aufweisen, die dem jeweils anderen Teil zugewandt sind. Die plattenförmige Ausbildung führt aber insgesamt zu einer sehr geringen Bauhöhe des Zwischenwirbelimplantates.

Bei einer bevorzugten Ausführungsform weisen sowohl das Unterteil als auch das Oberteil je eine Aufnahme für einen Gelenkeinsatz auf. Dieser Gelenkeinsatz, der nach dem Einsetzen des Zwischenwirbelimplantates zwischen Oberteil und Unterteil platziert wird, stützt Oberteil

- 6 -

und Unterteil gegeneinander ab, er übernimmt beispielsweise eine federnde Funktion und führt außerdem zu einer gewissen Verschwenkbarkeit der beiden Teile eines Zwischenwirbelimplantates gegeneinander, so daß damit auch eine Verschwenkbarkeit der benachbarten Wirbelkörper erreichbar ist.

Insbesondere ist es vorteilhaft, wenn der Gelenkeinsatz mindestens eine kugelige Stützfläche aufweist, die in die entsprechend kugelig geformte Aufnahme eingreift.

Günstig ist es, wenn die kugelige Aufnahme in einem zentralen Vorsprung des Oberteils angeordnet ist.

Es ist weiterhin vorteilhaft, wenn die zentrale Vertiefung des Unterteils die Aufnahme für den Gelenkeinsatz bildet.

Gemäß einer bevorzugten Ausführungsform der Erfindung ist vorgesehen, daß der Gelenkeinsatz von der Seite in die Aufnahme einschiebbar ist, die die Angriffselemente für ein Handhabungsinstrument trägt. Es handelt sich dabei um die Seite, von der Oberteil und Unterteil in den Zwischenwirbelraum eingeführt werden, und von dieser Seite her kann dann auch der Gelenkeinsatz zwischen die bereits eingesetzten Teile des Zwischenwirbelimplantats eingeschoben werden.

Dabei ist es günstig, wenn der Gelenkeinsatz längs einer Führung in die Aufnahme einschiebbar ist.

Auch der Einsatz ist vorzugsweise im wesentlichen plattenförmig ausgebildet.

- 7 -

Eine besonders günstige Ausgestaltung ergibt sich, wenn der Einsatz die zentrale Aufnahme im wesentlichen vollständig ausfüllt und mit der kugeligen Stützfläche aus der Aufnahme hervorsteht.

Die nachfolgende Beschreibung bevorzugter Ausführungsformen der Erfindung dient im Zusammenhang mit der Zeichnung der näheren Erläuterung. Es zeigen:

- Figur 1: eine perspektivische Explosionsansicht eines Zwischenwirbelimplantates mit einem Oberteil, einem Unterteil und einem zwischen diese einsetzbaren Gelenkeinsatz;
- Figur 2: eine perspektivische Explosionsansicht des Oberteils und des Unterteils des Zwischenwirbelimplantates ohne eingesetzten Gelenkeinsatz;
- Figur 3: eine Ansicht ähnlich Figur 2 mit in das Unterteil eingeschobenem Gelenkeinsatz;
- Figur 4: eine perspektivische Ansicht des Oberteils und des Unterteils des Zwischenwirbelimplantates in maximaler gegenseitiger Annäherung;
- Figur 5: eine Vorderansicht des Zwischenwirbelimplantats der Figur 4;

- 8 -

Figur 6: eine perspektivische Ansicht des Zwischenwirbelimplantates mit eingesetztem Gelenkeinsatz und

Figur 7: eine Querschnittsansicht des Zwischenwirbelimplantats der Figur 6.

Das in der Zeichnung dargestellte Zwischenwirbelimplantat 1 umfaßt drei Teile, nämlich ein plattenförmiges Oberteil 2, ein plattenförmiges Unterteil 3 und einen weitgehend plattenförmig ausgebildeten Gelenkeinsatz 4.

Das Oberteil 2 ist an seiner Oberseite eben ausgebildet, so daß dadurch eine Stützfläche 5 entsteht, auf der verschiedenartige Vorsprünge 6, 7 angeordnet sind, die der Verankerung des Oberteils 2 in einem Wirbelknochen dienen, der mit seiner einem Zwischenwirbelraum zugewandten Endfläche auf der Stützfläche 5 aufliegt.

Das Oberteil 2 hat einen im wesentlichen rechteckigen Querschnitt, wobei in dem dargestellten Ausführungsbeispiel eine Längskante 8 nach außen gebogen ist.

An den beiden Schmalseiten dieses Rechteckes ist die Dicke des plattenförmigen Oberteiles 2 kleiner als im zentralen Bereich, so daß sich längs der schmalen Seiten des Oberteils 2 jeweils parallel zu diesen Kanten verlaufende, nach unten weisende Rücksprünge 9 ausbilden, die zur Außenseite hin offen sind. Zwischen den beiden Rücksprüngen 9 befindet sich der zentrale Bereich des Oberteils 2, der somit eine größere Dicke oder Höhe aufweist und somit einen zwischen den beiden Rücksprüngen 9 ausgebildeten, nach unten weisenden Vor-

- 9 -

sprung 10 ausbildet. Dieser wird durch eine im wesentlichen parallel zur Stützfläche 5 verlaufende Unterseite 11 begrenzt, in der sich eine kugelige Vertiefung 12 befindet, diese bildet eine Lagerschale aus für den Gelenkeinsatz 4.

Das Unterteil 3 des Zwischenwirbelimplantates 1 ist ebenfalls plattenförmig ausgebildet und weist an seiner Unterseite eine ebene Stützfläche 13 mit Vorsprüngen 14 und 15 auf, die den Vorsprüngen 6 und 7 der Stützfläche 5 entsprechen. Auf der der Stützfläche 13 abgewandten Seite ist die Dicke des Unterteils 3 im zentralen Bereich geringer als in einem außenliegenden Bereich. Dieser außenliegende Bereich mit größerer Dicke hat die Form eines U mit zwei parallelen Schenkeln 16, 17, die parallel zu den Schmalkanten des im Querschnitt ähnlich wie das Oberteil 2 ausgebildeten Unterteiles 3 verlaufen, und mit einem die beiden Schenkel 16 und 17 an einer Seite verbindenden Steg 18. Der von den Schenkeln 16 und 17 und dem Steg 18 eingeschlossene Bereich bildet eine zentrale Vertiefung 19, deren Fläche im wesentlichen der Fläche des zentralen Vorsprunges 10 des Oberteils 2 entspricht, während die Anordnung und die Erstreckung der Schenkel 16 und 17 im wesentlichen der Anordnung und Erstreckung der Rücksprünge 9 am Oberteil 2 entsprechen. Es ist dadurch möglich, Oberteil 2 und Unterteil 3 so aufeinanderzulegen, daß der zentrale Vorsprung 10 des Oberteils 2 in die zentrale Vertiefung 19 eintaucht, während die Schenkel 16 und 17 des Unterteils 3 in die Rücksprünge 9 des Oberteils 2 eintauchen (Figur 4), in dieser Stellung sind Oberteil 2 und Unterteil 3 maximal einander angenähert und weisen eine minimale Bauhöhe auf.

- 10 -

Die Abmessungen sind dabei so gewählt, daß im wesentlichen die jeweiligen Rücksprünge durch die eintauchenden Vorsprünge vollständig ausgefüllt werden.

In die beiden Schenkel 16 und 17 des Unterteils 3 sind von deren freien Enden her parallel zu diesen Schenkeln 16, 17 verlaufend Sacklochbohrungen 20 und 21 eingearbeitet, deren Durchmesser im Verhältnis zur Höhe der Schenkel 16, 17 relativ groß ist, dieser Durchmesser ist tatsächlich größer als die Dicke oder Höhe des Unterteils 3 im Bereich der zentralen Vertiefung 19.

In den zentralen Vorsprung 10 des Oberteils 2 sind in der Nähe von dessen Seitenkanten Sacklochbohrungen 22 und 23 eingearbeitet, die parallel zu den Sacklochbohrungen 20 und 21 im Unterteil 3 verlaufen. Auch diese Sacklochbohrungen 22 und 23 haben einen relativ großen Durchmesser, der einem wesentlichen Teil der Höhe des Vorsprungs 10 entspricht und größer ist als die Dicke des Oberteils 2 im Bereich der Rücksprünge 9.

Wenn Oberteil 2 und Unterteil 3 in der beschriebenen Weise dicht aneinander anliegen, überlappen sich die Sacklochbohrungen 20 und 21 des Unterteils 3 und die Sacklochbohrungen 22 und 23 des Oberteils 2 in Richtung der Höhe des Zwischenwirbelimplantates 1 zumindest teilweise, wie dies aus der Darstellung der Figuren 4 und 5 deutlich wird.

Die Sacklochbohrungen 20, 21, 22 und 23 dienen als Aufnahmen für stiftförmige Verlängerungen eines in der Zeichnung nicht dargestellten Handhabungsinstrumentes

- 11 -

und bilden somit Angriffselemente für dieses Handhabungsinstrument, welches auf diese Weise getrennt am Oberteil 2 und am Unterteil 3 angreift. Es ist mit diesem Handhabungsinstrument möglich, Oberteil 2 und Unterteil 3 des Zwischenwirbelimplantates 1 in einen Zwischenwirbelraum einzuführen, dabei erleichtert die sehr geringe Bauhöhe des Zwischenwirbelimplantates 1 dieses Einführen, das im wesentlichen ohne große Aufweitung des Zwischenwirbelraumes möglich ist.

Nach dem Einführen des Oberteils 2 und des Unterteils 3 in diese Weise können die beiden Teile des Zwischenwirbelimplantates 1 aufgespreizt werden, d.h. ihr Abstand wird beispielsweise mit Hilfe des das Oberteil 2 und das Unterteil 3 haltenden Handhabungsinstrumentes vergrößert.

In dieser aufgespreizten Lage von Oberteil 2 und Unterteil 3 ist es möglich, den Gelenkeinsatz 4 zwischen Oberteil 2 und Unterteil 3 einzuschieben.

Dieser Gelenkeinsatz 4 ist im wesentlichen in Form einer Platte aufgebaut, die eine ebene Unterseite 24 und eine kugelig aufgewölbte Oberseite 25 aufweist. Die Außenabmessungen des plattenförmigen Gelenkeinsatzes 4 entsprechen denen der zentralen Vertiefung 19 im Unterteil 3, so daß der Gelenkeinsatz 4 diese Vertiefung ausfüllend in diese eingeschoben werden kann, und zwar von der Seite her, auf die sich die Sacklochbohrungen 20, 21, 22, 23 öffnen. Dabei greifen Führungsleisten 26 an den Seitenkanten des Gelenkeinsatzes 4 in entsprechende Führungsnuten 27 in den Schenkeln 16, 17 ein, so daß eine Einschubführung für den Gelenkeinsatz 4 gebil-

- 12 -

det wird, die diesen nach dem Einsetzen im Unterteil 3 festlegen. Der eingeschobene Gelenkeinsatz 4 füllt nach dem Einschieben die Vertiefung 19 aus und steht mit seiner kugelig gewölbten Oberseite 25 nach oben über die Oberseite des Unterteiles 3 hervor, die kugelige Oberseite 25 taucht dabei komplementär in die kugelig gewölbte Vertiefung 12 an der Unterseite des Vorsprungs 10 ein und bildet dort mit Oberteil 2 ein Kugelgelenk aus, welches eine gewisse Verschwenkbarkeit des Oberteils 2 gegenüber dem Unterteil 3 ermöglicht (Figur 7).

Der Gelenkeinsatz 4 kann an seiner ebenen Unterseite 24 einen Rastvorsprung 28 tragen, der beim Einschieben des Gelenkeinsatzes 4 in das Unterteil 3 elastisch in eine Rastausnehmung 29 einrastet, die sich am Boden der Vertiefung 19 befindet; dadurch wird der Gelenkeinsatz 4 auch in Einschubrichtung in der Vertiefung 19 festgelegt.

Oberteil 2 und Unterteil 3 sind vorzugsweise aus körperverträglichem Metall hergestellt, beispielsweise aus Titan, während der Gelenkeinsatz 4 vorzugsweise aus einem ebenfalls körperverträglichen Kunststoffmaterial besteht, beispielsweise aus Polyethylen. Diese Stützflächen 5 bzw. 13 können besonders knochenverträglich ausgebildet sein, beispielsweise kann diese Fläche durch eine Beschichtung aufgerauht werden, so daß sich eine optimale Verankerung mit dem benachbarten Knochenmaterial ergibt.

PATENTANSPRÜCHE

1. Zwischenwirbelimplantat (1) mit einem eine Stützfläche (5) für einen Wirbelkörper aufweisenden Oberteil (2) und einem eine Stützfläche (13) für einen benachbarten Wirbelkörper aufweisenden Unterteil (3), an denen jeweils von einer Seite des Zwischenwirbelimplantats her zugängliche Angriffselemente (20, 21, 22, 23) für ein Handhabungsinstrument angeordnet sind, dadurch gekennzeichnet, daß Oberteil (2) und Unterteil (3) jeweils zum anderen Teil gerichtete Vor- bzw. Rücksprünge (10, 19; 16, 17, 9) aufweisen, die seitlich so gegeneinander versetzt sind, daß sie bei an das Unterteil (3) angenähertem Oberteil (2) ineinander eingreifen, und daß die Angriffselemente (22, 23; 20, 21) am Oberteil (2) und am Unterteil (3) jeweils in Vorsprüngen (10; 16, 17) dieser Teile derart angeordnet sind, daß die Angriffselemente (22, 23; 20, 21) von Oberteil (2) und Unterteil (3) nebeneinander liegen und sich in Richtung der Höhe des Zwischenwirbelimplantats (1) zumindest teilweise überlappen.
2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Angriffselemente (20, 21, 22, 23) Einstecköffnungen für stiftförmige Halteelemente eines Handhabungsinstrumentes sind.

- 14 -

3. Implantat nach Anspruch 2, dadurch gekennzeichnet, daß sich die Einstecköffnungen (20, 21, 22, 23) im wesentlichen parallel zu den Stützflächen (5; 13) erstrecken.
4. Implantat nach einem der voranstehenden Ansprüche, dadurch gekennzeichnet, daß das Unterteil (3) eine der unteren Stützfläche (13) gegenüberliegende zentrale Vertiefung (19) aufweist, die von einem U-förmigen Rand (16, 17, 18) umgeben ist.
5. Implantat nach Anspruch 4, dadurch gekennzeichnet, daß das Oberteil (2) einen im wesentlichen komplementär in die Vertiefung (19) passenden zentralen Vorsprung (10) trägt.
6. Implantat nach einem der Ansprüche 4 oder 5, dadurch gekennzeichnet, daß die Angriffselemente (20, 21) des Unterteils (3) an den beiden Enden des U-förmigen Randes (16, 17, 18) angeordnet sind.
7. Implantat nach einem der Ansprüche 5 oder 6, dadurch gekennzeichnet, daß die Angriffselemente (22, 23) des Oberteils (2) an dem zentralen Vorsprung (10) des Oberteils (2) angeordnet sind.

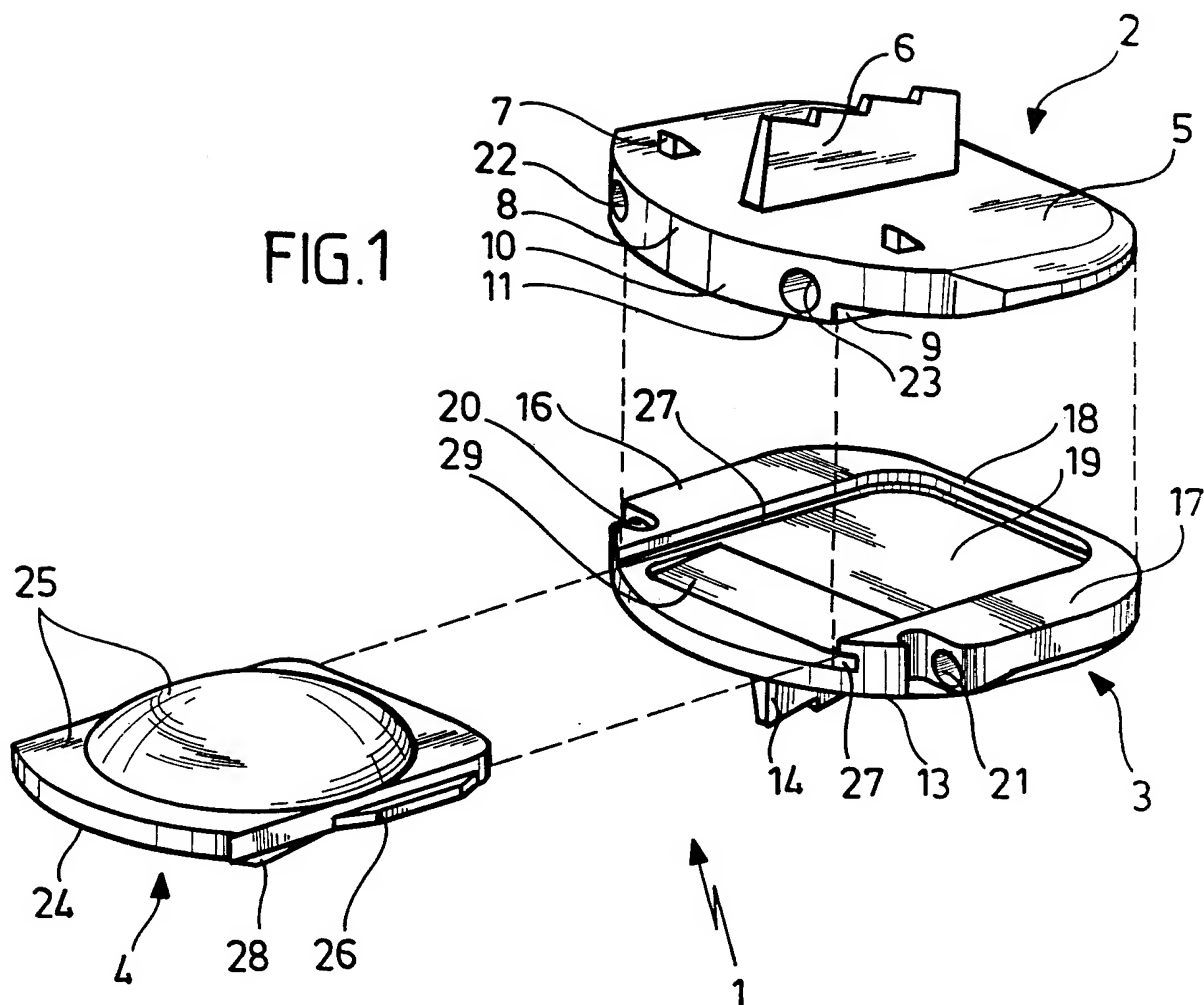
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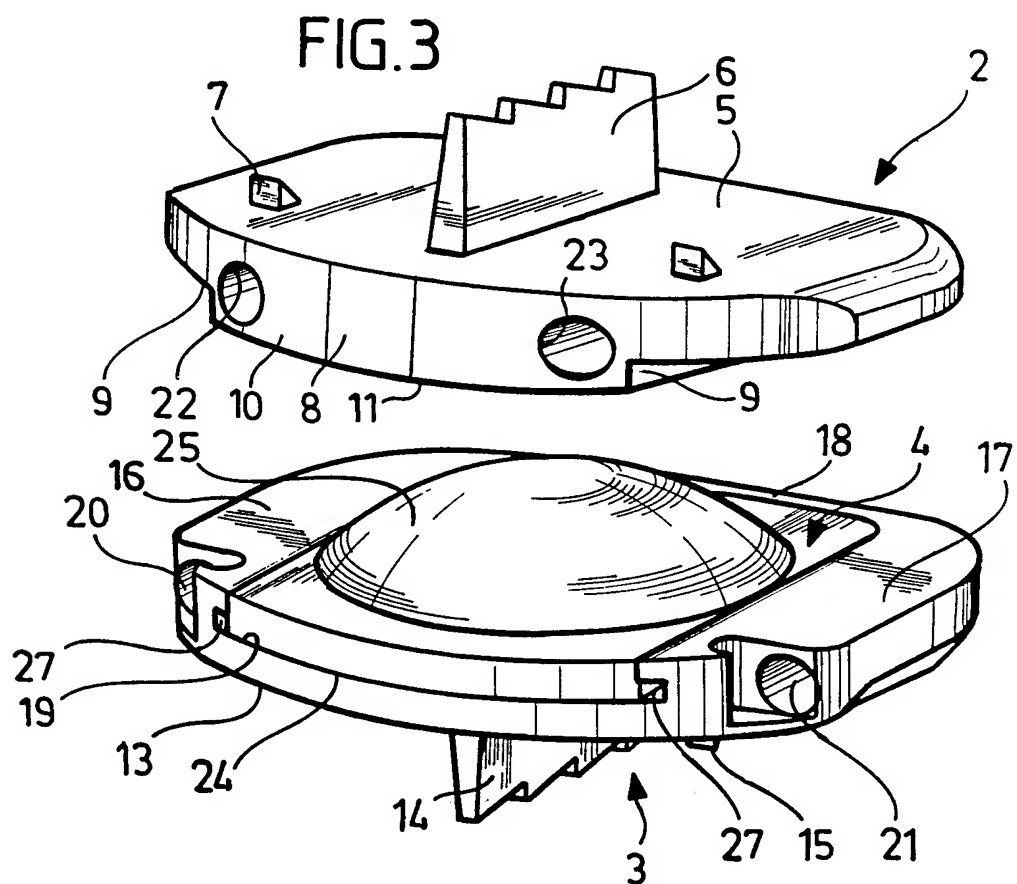
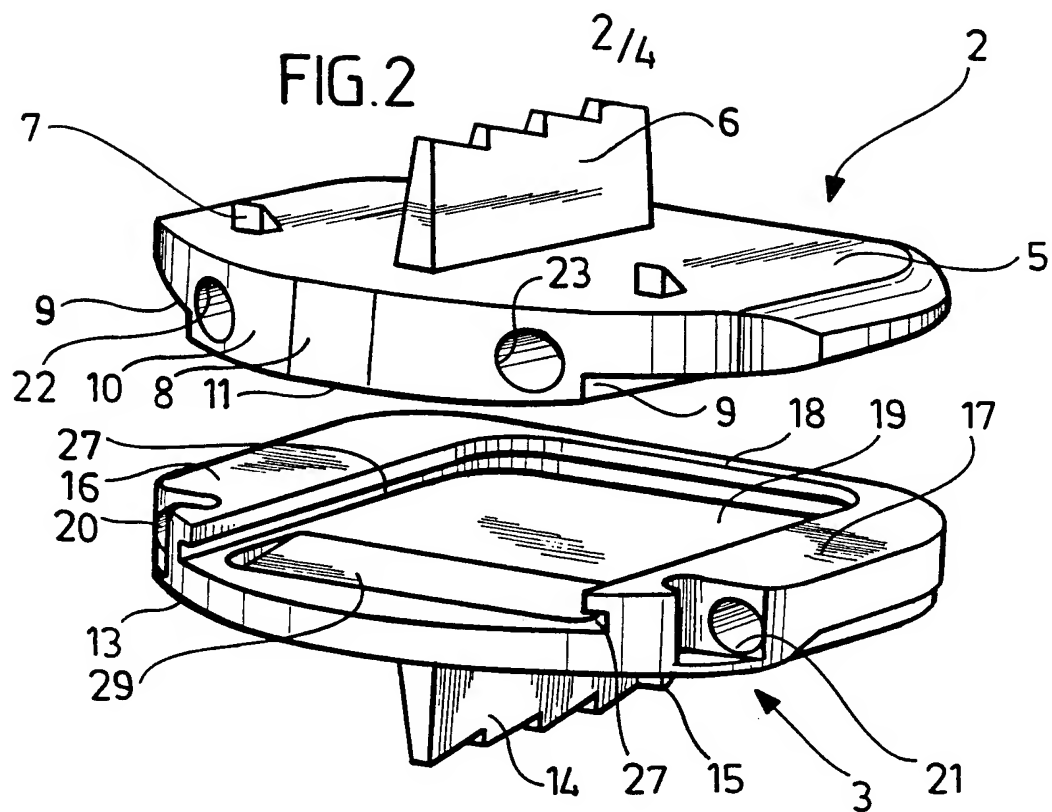
8. Implantat nach Anspruch 7, dadurch gekennzeichnet, daß die Angriffselemente (22, 23) des Oberteils (2) nahe der seitlichen Ränder des zentralen Vorsprungs (10) angeordnet sind.
9. Implantat nach einem der voranstehenden Ansprüche, dadurch gekennzeichnet, daß das Oberteil (2) und/oder das Unterteil (3) im wesentlichen plattenförmig ausgebildet sind.
10. Implantat nach einem der voranstehenden Ansprüche, dadurch gekennzeichnet, daß das Unterteil (3) und das Oberteil (2) je eine Aufnahme (19; 12) für einen Gelenkeinsatz (4) aufweisen.
11. Implantat nach Anspruch 10, dadurch gekennzeichnet, daß der Gelenkeinsatz (4) mindestens eine kugelige Stützfläche (25) aufweist, die in die entsprechend kugelig geformte Aufnahme (12) eingreift.
12. Implantat nach Anspruch 11, dadurch gekennzeichnet, daß die kugelige Aufnahme (12) in dem zentralen Vorsprung (10) des Oberteils (2) angeordnet ist.

- 16 -

13. Implantat nach einem der Ansprüche 10 bis 12, dadurch gekennzeichnet, daß die zentrale Vertiefung (19) des Unterteils (3) die Aufnahme für den Gelenkeinsatz (4) bildet.
14. Implantat nach Anspruch 13, dadurch gekennzeichnet, daß der Gelenkeinsatz (4) von der Seite in die Aufnahme (19) einschiebbar ist, die die Angriffselemente (20, 21, 22, 23) für ein Handhabungsinstrument trägt.
15. Implantat nach Anspruch 14, dadurch gekennzeichnet, daß der Gelenkeinsatz (4) längs einer Führung (26, 27) in die Aufnahme (19) einschiebbar ist.
16. Implantat nach einem der Ansprüche 10 bis 15, dadurch gekennzeichnet, daß der Gelenkeinsatz (4) im wesentlichen plattenförmig ausgebildet ist.
17. Implantat nach einem der Ansprüche 11 bis 16, dadurch gekennzeichnet, daß der Gelenkeinsatz (4) die zentrale Aufnahme (19) im wesentlichen vollständig ausfüllt und mit der kugeligen Stützfläche (25) aus der Aufnahme (19) hervorsteht.

1/4





3/4

FIG.4

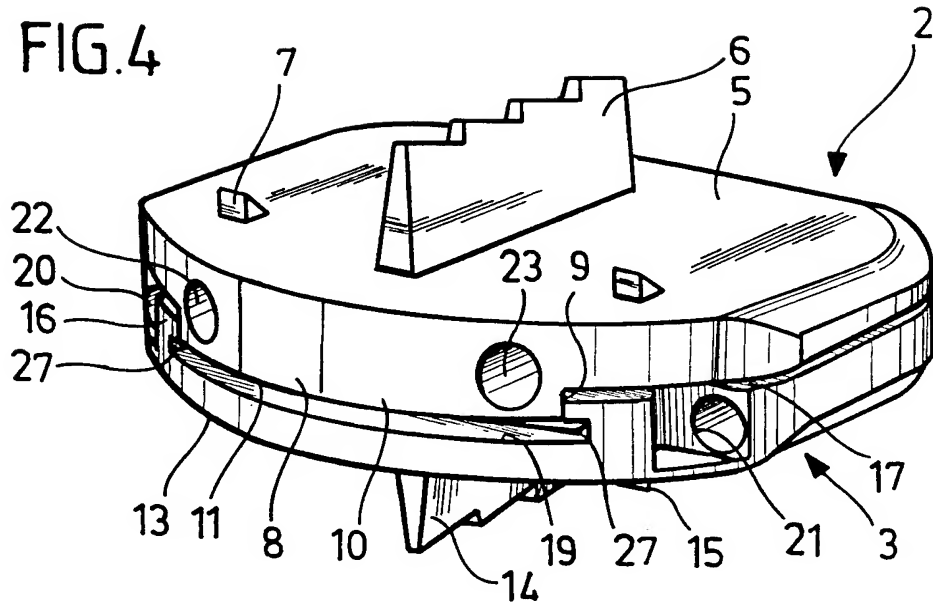
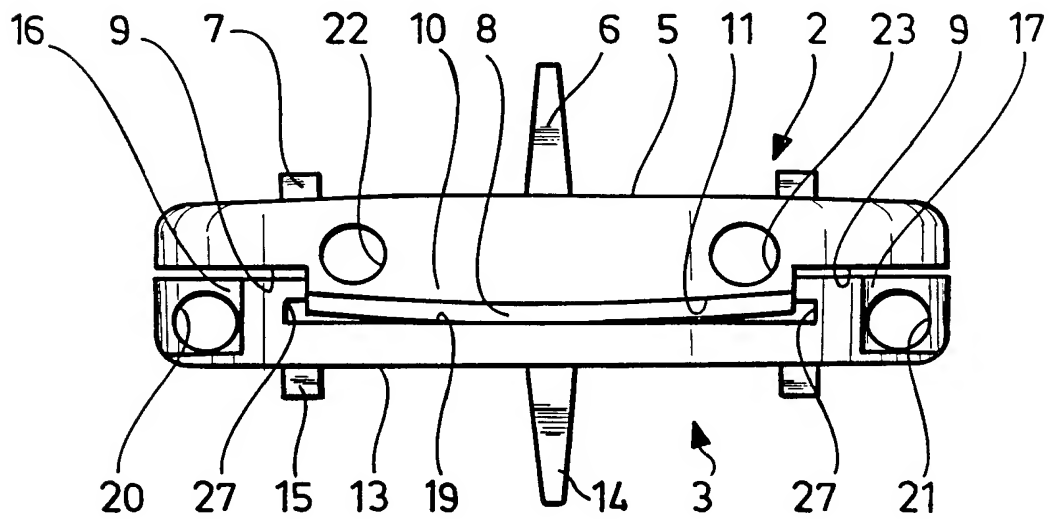


FIG.5



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FIG.6

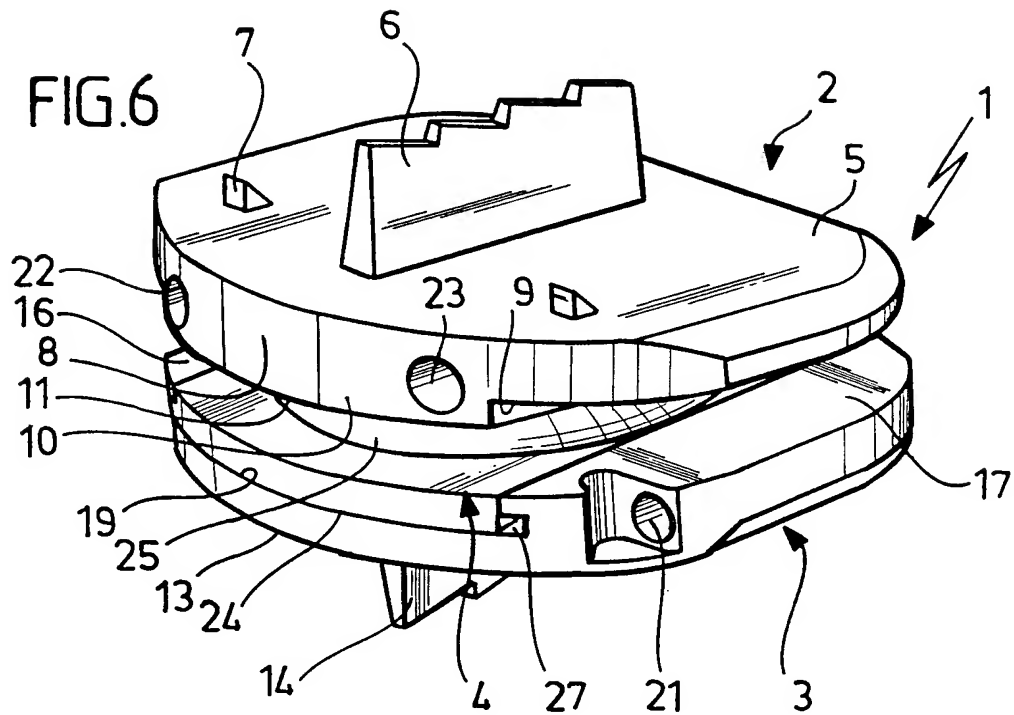
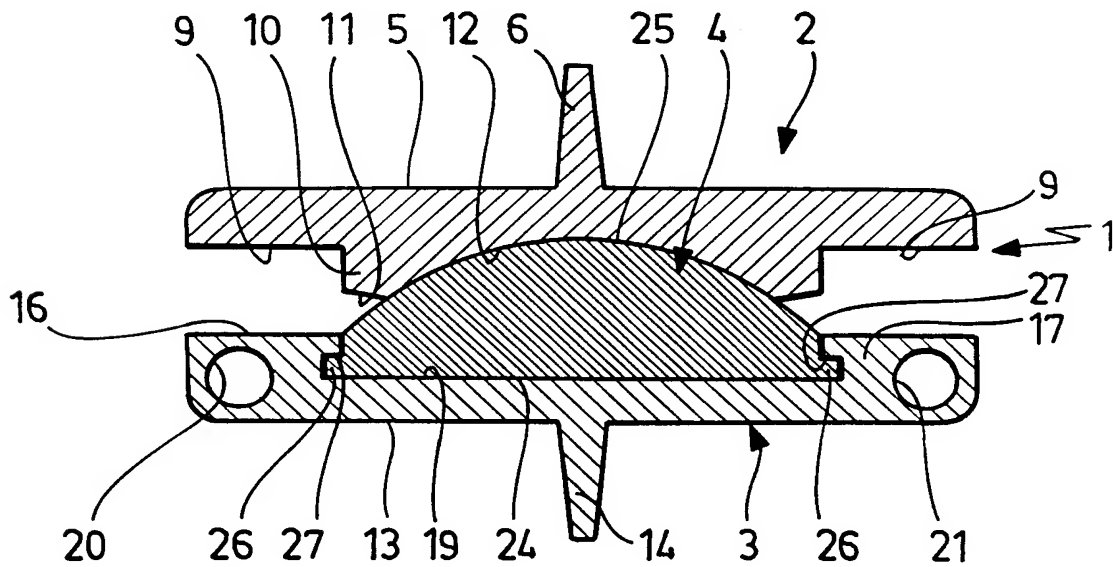


FIG.7



INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 314 477 A (MARNAY THIERRY) 24 May 1994 (1994-05-24) cited in the application figures 1-3,10 claim 1	1-5, 9-13,17
A	FR 2 718 635 A (AXCYL MEDICAL) 20 October 1995 (1995-10-20) figures 2,4,7,8,11 claims 1-3	1,9-11, 13-15,17
A	WO 98 14142 A (SURGICAL DYNAMICS INC) 9 April 1998 (1998-04-09) figures 13-20	1,9, 11-13
A	EP 0 333 990 A (LINK WALDEMAR GMBH CO) 27 September 1989 (1989-09-27)	



Further documents are listed in the continuation of box C.



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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5314477 A	24-05-1994	FR 2659226 A AT 106707 T AU 7499191 A DE 69102369 D DE 69102369 T EP 0471821 A ES 2057874 T WO 9113598 A JP 2889696 B JP 4505574 T	13-09-1991 15-06-1994 10-10-1991 14-07-1994 05-01-1995 26-02-1992 16-10-1994 19-09-1991 10-05-1999 01-10-1992
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INTERNATIONALER RECHERCHENBERICHT

Internationales Abkürzungszeichen

PCT/EP 99/04628

A. KLASIFIZIERUNG DES ANMELDUNGSGEGENSTANDES

IPK 7 A61F2/44

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IPK 7 A61F

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	US 5 314 477 A (MARNAY THIERRY) 24. Mai 1994 (1994-05-24) in der Anmeldung erwähnt Abbildungen 1-3, 10 Anspruch 1	1-5, 9-13, 17
A	FR 2 718 635 A (AXCYL MEDICAL) 20. Oktober 1995 (1995-10-20) Abbildungen 2, 4, 7, 8, 11 Ansprüche 1-3	1, 9-11, 13-15, 17
A	WO 98 14142 A (SURGICAL DYNAMICS INC) 9. April 1998 (1998-04-09) Abbildungen 13-20	1, 9, 11-13
A	EP 0 333 990 A (LINK WALDEMAR GMBH CO) 27. September 1989 (1989-09-27)	



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INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

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Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
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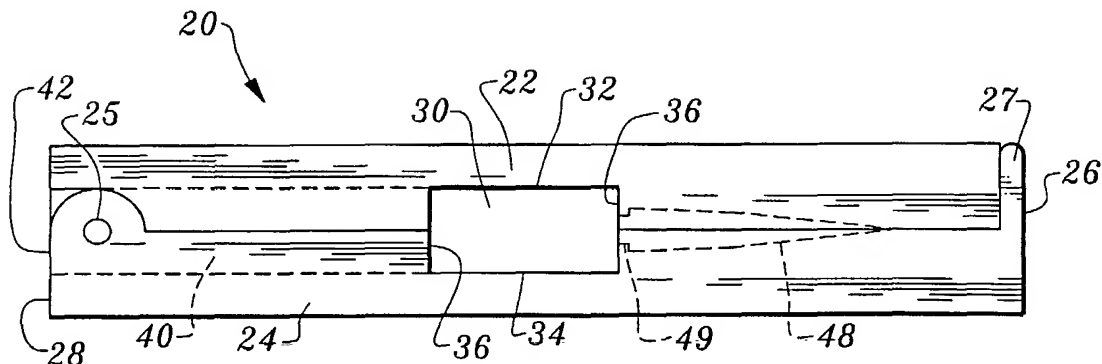
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(54) Title: INTERVERTEBRAL SPACE IMPLANT FOR USE IN SPINAL FUSION PROCEDURES



(57) **Abstract:** An implant assembly (10) is provided for surgical implantation into an intervertebral space (S) such as for stabilization of vertebrae (V) adjacent the intervertebral space (S) during a spinal fusion procedure. The implant assembly (10) includes a primary segment (20) separate from a secondary segment (60). These segments (20, 60) are elongate and of sufficiently small cross-section that they can be implanted posteriorly in a minimally invasive manner. The primary segment (20) preferably includes a tunnel (30) and the secondary segment (60) preferably includes a neck (70) with the tunnel (30) and neck (70) sized complementary so that the segments (20, 60) stabilize each other where they intersect with the neck (70) within the tunnel (30). The entire implant assembly (10) is thus provided which both widens and supports the intervertebral space (S) and is sufficiently rigid to provide adequate support for the intervertebral space (S) as the vertebrae (V) are fusing together.



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INTERVERTEBRAL SPACE IMPLANT FOR USE IN SPINAL FUSION PROCEDURES

5

Technical Field

10 The following invention relates to implants which are configured to be placed within an intervertebral space between adjacent spinal vertebrae after a disk has been removed from the space and to facilitate fusion of the vertebrae together. More particularly, this invention relates to implants which can be implanted posteriorly in either a minimally invasive or open manner and spread vertebrae adjacent the intervertebral space away from each other to recreate the lumbar lordosis and
15 support the vertebrae while they fuse together.

Background Art

20 Spinal fusion procedures are known as an effective treatment for certain spinal conditions. In general, such spinal fusion procedures may involve removal of a disk within an intervertebral space between two adjacent vertebrae. After the disk has been removed an implant can be located within the intervertebral space to push the vertebrae apart. By pushing the vertebrae apart, ligaments and other body structures surrounding the vertebrae are placed in tension and tend, along with the
25 implant, to securely hold the two vertebrae in fixed position relative to each other. It is important to restore as much as possible the height of the intervertebral space. It is also important to restore the angle or "lordosis" of the intervertebral space. Finally, fusion material is placed within the intervertebral space which induces bone growth within the intervertebral space, effectively fusing the two vertebrae together with the implant typically remaining embedded within this fused vertebra
30 combination.

Placement of the implant within the intervertebral space is accomplished in one of two general ways. First, the intervertebral space can be accessed anteriorly by performing abdominal/thoracic surgery on the patient and accessing the intervertebral space from a front side of the patient. In this anterior procedure major abdominal/thoracic surgery is typically involved. However, the
35 intervertebral space can be generally accessed anteriorly, such that the risk of injury to the nerves is generally reduced and the surgeon has greater flexibility in positioning the implant precisely where desired.

Second, the implant can be inserted posteriorly. Direct posterior access to the intervertebral space requires moving the spinal nerves within the spinal canal towards the midline and can result in nerve injury or scarring. Implantation in the intervertebral space can also be accessed from a location spaced to the left or right side of the spinal column and at an angle extending into the intervertebral space. This approach avoids the spinal canal. A minimally invasive method using small incisions can be used but is must be carefully performed to avoid sensitive spinal structures. Additionally, implants of a smaller size are typically required due to the small amount of clearance between vertebral structures. Hence, the amount of spreading of the vertebrae with a posterior implant is often less than adequate. Additionally, portions of the vertebrae typically need to be at least partially carved away to provide the access necessary to insert the implants posteriorly into the intervertebral space.

Implants for the intervertebral space come in a variety of different configurations, most of which are designed for anterior implantation. One known prior art implant is described in detail in United States Patent No. 5,800,550 to Sertich. The Sertich implant is configured to be implanted posteriorly and comes in two pieces. Two separate incisions are made on either side of the spine and the pieces of the overall implant are inserted generally parallel to each other, but can be angled slightly away from a parallel orientation. The Sertich implant pieces have a rectangular cross section and an elongate form. The pieces are initially implanted with a lesser dimension oriented vertically so that the pieces can easily enter the intervertebral space. The pieces are then rotated 90° so that the greater dimension is rotated to vertical, tending to spread the vertebrae vertically to enlarge the intervertebral space.

The implant taught by Sertich is not entirely desirable. Because the Sertich implant involves two entirely separate pieces, they do not stabilize each other in any way and hence provide a less than ideal amount of vertebral stabilization. Additionally, the relatively parallel angle at which they are implanted typically requires removal of portions of the vertebrae and retraction of the spinal nerves to properly implant the pieces of the Sertich implant. If the two pieces of the implant are angled more towards each other, they tend to decrease further in the stability that they provide to the vertebrae. Also, the Sertich implant pieces have a size which requires a relatively large incision to insert into the intervertebral space.

Accordingly, a need exists for a posteriorly placed intervertebral space implant which has a small cross-sectional profile at insertion and yet can provide a large amount of displacement between adjacent vertebrae once placed. The implant must expand sufficiently far apart to restore the height of the intervertebral space and act substantially as a single rigid structure within the intervertebral space after implantation is completed. Such an invention would additionally benefit from being capable of having a greater height in an anterior region such that lordosis can be achieved in an amount desired by the surgeon with an anterior side of the intervertebral space larger than a posterior side of the intervertebral space.

Disclosure of Invention

This invention is an intervertebral space implant which is configured to be implanted posteriorly in a minimally invasive or open surgical procedure. The implant includes two separate segments including a primary segment and a secondary segment. The primary segment and the secondary segment enter the intervertebral space through separate incisions on either side of the spine and along paths which intersect within the intervertebral space. To enhance a spreading of the intervertebral space with the implant, the segments have a height between a bottom surface and a top surface which is greater than a lateral width. The segments can thus be introduced into the intervertebral space with the top and bottom surfaces spaced laterally from each other and then be rotated 90° so that the top surface is above the bottom surface and a height of the segments is maximized.

Portions of the primary segment and the secondary segment adjacent where the segments intersect are removed to allow the segments to lie in a substantially common plane. Preferably, the primary segment includes a tunnel passing laterally through the primary segment near a midpoint thereof. The secondary segment is provided with a neck near a midpoint thereof which has a lesser height than other portions of the secondary segment. The tunnel is sized so that the secondary segment can pass through the tunnel in the primary segment and then be rotated with the neck of the secondary segment within the tunnel of the primary segment.

After the secondary segment has been rotated the two segments are interlocking together in a crossing pattern forming the implant assembly of this invention. Hence, the implant assembly of this invention provides the advantage of having a relatively low profile for insertion posteriorly in a minimally invasive manner and yet results in an overall implant assembly which has separate segments interlocking together to form a single substantially rigid implant assembly to maximize stabilization of the vertebrae adjacent the intervertebral space.

Additionally, the segments are formed in a manner which facilitates height expansion of the segments after implantation, especially at distal ends of the segments. Such additional height expansion further stabilizes vertebrae adjacent the intervertebral space and provides lordosis to the intervertebral space.

Specifically, the primary segment is preferably formed with a top structure separate from a bottom structure which pivot relative to each other, such as about a hinge. A passage passes between the top structure and the bottom structure. A shim can pass along the passage and cause a distal end of the primary segment to be expanded in height when the shim enters a tapering end portion of the passage. The distal end of the primary segment is thus expanded in height to an extent desired by a surgeon to provide a desirable amount of "lordosis" for the spinal fusion procedure.

Similarly, the secondary segment is preferably formed from a top jaw and a bottom jaw which can pivot relative to each other, such as about a hinge. A bore passes between the top jaw and the

bottom jaw and a wedge is caused to move within the bore in a manner causing the top jaw and the bottom jaw to be spaced apart and causing a height of the secondary segment to be increased at a first distal end of the secondary segment.

The insertion of the segments themselves as well as the movement of shims and wedges within the segments to enhance their height is all accomplished through a small posterior incision. A variety of different hinge arrangements, shim and wedge arrangements and other structural variations are provided for the segments of the implant assembly.

10 Brief Description of Drawings

Figure 1 is a side elevation view of a human spine with an intervertebral space containing the implant assembly of this invention.

Figures 2-5 are top plan views taken along line 5-5 of Figure 1 illustrating the four basic steps involved in the implantation of the implant assembly of this invention.

Figure 6 is a side elevation view of a primary segment of the implant assembly with hollow interior details shown in broken lines.

Figure 7 is a top plan view of that which is shown in Figure 6.

Figure 8 is a proximal end elevation view of that which is shown in Figure 6.

Figure 9 is a full sectional view of that which is shown in Figure 6 and with a guide wire and shim of this invention shown entering a passage within the primary segment to expand a height of the primary segment adjacent a distal end of the primary segment.

Figure 10 is a full sectional view of that which is shown in Figure 9 after the shim has been fully advanced into the passage of the primary segment of this invention so that the height of the distal end of the primary segment has been enhanced.

Figure 11 is a full sectional side elevation view of a secondary segment of the implant assembly of this invention along with one form of a tool utilized to enhance a height of a distal first end of the secondary segment of the implant assembly of this invention.

Figure 12 is a top plan view of that which is shown in Figure 11 with interior details shown with broken lines.

Figure 13 is a proximal second end view of that which is shown in Figure 12.

Figure 14 is a full sectional view of that which is shown in Figure 11 after a wedge has been fully advanced to enhance a height of the distal first end of the secondary segment.

Figure 15 is a top plan view of a tongs identifying one form of tool utilizable to implant the primary segment or the secondary segment of this invention.

Figure 16 is a side elevation view of an alternative embodiment of that which is shown in Figure 6 showing an offset hinge.

Figure 17 is a proximal end view of that which is shown in Figure 16.

Figure 18 is a proximal end view of a second alternative embodiment of the primary segment of this invention.

Figure 19 is a side elevation view of a third alternative embodiment of a primary segment of the implant assembly of this invention with interior details shown with broken lines.

5 Figure 20 is a distal end view of that which is shown in Figure 19.

Figure 21 is a side elevation view of that which is shown in Figure 19 after full advancement of an alternative shim for use with the third alternative primary segment of the implant assembly of this invention.

10 Figure 22 is a full sectional side elevation view of a fourth alternative embodiment of a primary segment of the implant assembly of this invention showing a guide wire with both a shim advanced past a tunnel in the fourth alternative primary segment and a proximal shim and expanding hinge to allow height expansion of a proximal end of the fourth alternative primary segment of the implant assembly of this invention.

15 Figure 23 is a full sectional side elevation view of that which is shown in Figure 22 after insertion of the proximal shim of this embodiment into a proximal recess to enhance the proximal height of the fourth alternative primary segment of the implant assembly of this invention.

Figures 24-27 are sectional and side elevation views of an expanding hinge of the fourth alternative primary segment of the implant assembly of this invention revealing in detail the various stages in the operation of this expanding hinge.

20 Figures 28-30 are top plan views of alternatives of the implant assembly of this invention showing how various beveled surfaces and relief notches can be provided adjacent the tunnel in the primary segment and the neck in the secondary segment to facilitate rotation of the secondary segment within the tunnel of the primary segment and to facilitate orientation of the secondary segment at an angle relative to the primary segment other than purely a perpendicular angle.

25

Best Modes for Carrying Out the Invention

30 Referring to the drawings, wherein like reference numerals represent like parts throughout the various drawing figures, reference numeral 10 (Figure 1) is directed to an implant assembly for implantation into an intervertebral space S between adjacent vertebrae V after a disk D has been removed from the intervertebral space S. A primary segment 20 and a secondary segment 60 are implanted along separate pathways but interlock together within the intervertebral space S to form a single implant assembly 10. The resulting assembly 10 securely stabilizes the vertebrae V adjacent
35 the intervertebral space S for spinal fusion of the vertebrae V together.

In essence, and with particular reference to Figures 1-5, the basic details of the implant assembly 10 are described. The implant assembly 10 includes a primary segment 20 (Figure 2) and a secondary segment 60 (Figure 4). The primary segment 20 is elongate in form extending along a

primary axis A. The primary segment 20 is preferably higher than it is wide (compare Figure 2 with Figure 3), thus having a rectangular cross-section. The primary segment 20 can thus be inserted on its side into the intervertebral space (along arrow C of Figure 2) and then rotated within the intervertebral space (along arrow F of Figure 3) to help spread vertebrae V adjacent the intervertebral space S away from each other. The primary segment 20 additionally includes a tunnel 30 (Figure 2) passing laterally through the primary segment 20.

The secondary segment 60 (Figure 4) is elongate and has a contour generally similar to that of the primary segment 20. However, the secondary segment 60 includes a neck 70 rather than the tunnel 30 of the primary segment 20. The secondary segment 60 has a cross-sectional size similar to a size of the tunnel 30. This size allows the secondary segment 60 to be inserted along secondary axis B (in the direction identified by arrow E of Figure 4) through the tunnel 30 in the primary segment 20. The secondary segment 60 can later be rotated (along arrow G of Figure 5) in a manner similar to the rotation of the primary segment 20 so that a height of the secondary segment 60 is oriented vertically and maximizes a spacing of vertebrae V adjacent the intervertebral space S. The segments 20, 60 interlock together to form the implant assembly 10 with the segments 20, 60 stabilizing each other and allowing the implant assembly 10 to stabilize the intervertebral spaces in which the assembly 10 is implanted.

More specifically, and with particular reference to Figures 6-10, details of the primary segment 20 according to a preferred embodiment of this invention are described. The primary segment 20 is an elongate substantially rigid construct formed from a top structure 22 and a bottom structure 24 which are pivotably joined together, such with a hinge 25. The hinge 25 can take on many different forms to provide the basic function of allowing the top structure 22 and the bottom structure 24 to be pivoted relative to each other.

The primary segment 20 extends from a distal end 26 to a proximal end 28. A guide wire stop 27 can be optionally included with the bottom structure 24 at the distal end 26 and extend up beyond the top structure 22.

The tunnel 30 passes laterally through the primary segment 20 between a top surface and a bottom surface of the primary segment 20. The tunnel 30 includes a top 32 preferably substantially parallel to a bottom 34 and sides 36 extending between the bottom 34 and the top 32. The tunnel 30 preferably has dimensions similar to exterior dimensions of the primary segment 20 itself, but rotated 90°. The tunnel 30 is thus sized to allow secondary segments 60 with dimensions similar to the primary segment 20 to pass laterally through the tunnel 30 during formation of the implant assembly 10 of this invention within the intervertebral space S (Figures 1-5).

A passage 40 extends longitudinally within the primary segment 20 and between the top structure 22 and the bottom structure 24. The passage 40 includes an entrance 42 at the proximal end 28 of the primary segment. The passage 40 additionally includes a roof 44 preferably substantially parallel to and spaced from a floor 46. Preferably, the passage 40 has a constant cross-section from the entrance 42 to a location where the passage 40 intersects the tunnel 30. The

passage 40 preferably continues beyond the tunnel 30 and toward the distal end 26 of the primary segment 20. However, portions of the passage 40 on a distal side of the tunnel 30 preferably taper to form a tapering end 48 of the passage 40. A step 49 is preferably located in the passage 40 directly adjacent the tunnel 30.

5 The passage 40 is configured to receive a shim 50 therein. The shim 50 (Figure 9) preferably has a rectangular cross-section which generally fills the passage 40 (Figure 8) so that the shim does not rotate. The shim 50 preferably includes a tip 52 which is of lesser height than a tail 54. A central pathway 56 preferably passes through the shim 50. A guide wire 58 can be passed entirely through the passage 40 up to the stop 27 (along arrow H of Figure 9) and then the shim 50
10 threaded onto the guide wire 58. The shim 50 can then be easily advanced along the guide wire 58 (arrow J of Figure 9) and directed into the passage 40. When the shim 50 reaches the tapering end 48 of the passage 40, with the assistance of an appropriate shim pushing tool, the shim 50 causes the top structure 22 and bottom structure 24 of the primary segment 20 to be expanded away from each other (about arrow K of Figure 10) and a height of the primary segment 20 to be enhanced at
15 the distal end 26 of the primary segment 20.

Such distal end 26 height expansion for the primary segment 20 is desirable in many cases to provide lordosis to the intervertebral space S. Specifically, lordosis is a orientation for the intervertebral space S where an anterior edge of the intervertebral space S has a greater height than a posterior edge of the intervertebral space S. Such lordosis can be provided to a varying degree
20 depending on the desires of the medical practitioner. With this invention the shim 50 is advanced an amount desired through the passage 40 of the primary segment 20 to provide an amount of lordosis which is desirable in the judgment of the medical practitioner. The segment 20 can be custom designed to provide the lordosis desired or can be variably expandable for adjustment during implantation.

25 With particular reference to Figures 11-14, details of a preferred embodiment of the secondary segment 60 are described. The secondary segment 60 preferably has a general exterior contour similar to that of the primary segment 20. Also, the secondary segment 60 is preferably divided into a top jaw 62 and a bottom jaw 64 which are pivotably connected together, such as at a hinge 65. As with the primary segment 20, the hinge 65 can take on a variety of different configurations. The
30 secondary segment 60 extends from a first distal end 66 to a second proximal end 68.

The secondary segment 60 includes a neck 70 with two preferably substantially parallel surfaces 72 and side walls 74 extending between the parallel surfaces 72 of the neck 70 and top and bottom surfaces of the secondary segment 60. The side walls 74 can be perpendicular to the parallel surfaces 72 (as depicted generally in Figure 4) or can be beveled (as shown in Figure 11). The
35 parallel surfaces 72 are located closer to each other than a distance between top and bottom surfaces of the secondary segment 60. The parallel surfaces 72 need not be precisely parallel, but benefit from having a lesser height than that of the top and bottom surfaces of the secondary segment 60 so that the neck 70 of the secondary segment 60 is an open region then can reside within the tunnel

30 or other open region in the primary segment 20 after rotation of the secondary segment 60 into an orientation with the top surface and the bottom surface vertically aligned along with top and bottom surfaces of the primary segment 20 (Figure 5). Preferably, the neck 70 is located near a midpoint between the distal first end 66 and the proximal second end 68 of the secondary segment 60.

The width between lateral sides of the secondary segment 60 is preferably similar to a height of the neck 70 and a height of the tunnel 30 in the primary segment 20 for a tight fit within the tunnel 30 both before and after rotation (about arrow G of Figure 5). The hinge 25 in the primary segment 20, general slight flexibility of the segments 20, 60 and possible slight additional clearances can provide the relief necessary to allow the secondary segment 60 to rotate with the neck 70 within the tunnel 30. Preferably, the secondary segment 60 tends to snap into its final position so that the segments 20, 60 are securely interlocked together.

To provide lordosis to the intervertebral space S, the secondary segment 60 is configured to allow height expansion, particularly at the distal first end 66. Specifically, the secondary segment 60 includes a bore 80 passing longitudinally from the proximal second end 68, at least part of the way toward the distal first end 66. The bore 60 includes a pin 82 therein which includes a threaded end 83 at an end thereof closest to the distal first end 66 of the secondary segment 60. An access end 84 of the pin 82 is opposite the threaded end 83 and closest to the proximal second end 68 of the secondary segment 60. A wrench 85 having one of a variety of different configurations (Figure 11) can be utilized to cause the pin 82 to rotate by interaction of the wrench 85 with the access end 84 of the pin 82. Preferably, the bore 80 is slightly smaller adjacent the proximal end 68 to keep the pin 82 from sliding toward the proximal end 68 within the bore 80.

A wedge 86 is located within a tapering recess 87 in the bore 80. The wedge 86 is preferably cylindrical and includes a threaded hole extending perpendicularly through curving sides of the wedge into which the threaded end 83 of the pin 82 is located. Hence, when the pin 82 is rotated by rotation of the tool 85 (along arrow L of Figure 11) the threaded end 83 of the pin 82 causes the wedge 86 to travel toward the distal first end 66 of the secondary segment 60 (along arrow M of Figure 14). As the wedge 86 travels toward the distal first end 66 and through the tapering recess 87, the top jaw 62 and bottom jaw 64 are spread vertically (along arrow N of Figure 14), enhancing a height of the secondary segment 60.

While the primary segment 20 and secondary segment 60 are shown with unique systems for vertically expanding top and bottom portions of the segments 20, 60, it is noted that these systems are merely one currently most preferred embodiments of a vertical height enhancement system for the segments 20, 60. In fact, a variety of different systems could be utilized to enhance the vertical height of the segments 20, 60 after implantation.

Most preferably, the segments 20, 60 have a height between a top and bottom surface approximately twice a width between lateral sides of the segments 20, 60. A tongs 90 (Figure 15) can be utilized to properly place the segments 20, 60 within the intervertebral space S (Figure 1).

Tongs 90 typically have fingers 92 which have tips 93 with a width similar to half of the lateral width of the segments 20. In this way, the segments 20, 60 could be grasped on lateral sides with the tips 93 of the fingers 92 of the tongs 90 and the segments 20, 60 can be advanced through a tubular cannula with the tubular cannula having a diameter similar to a height of the segments 20, 60 between top and bottom surfaces of the segments 20, 60. The tongs 90 might include a pivot 94 with handles 96 at ends of the tongs 90 opposite the fingers 92 for releasably grasping the segments 20, 60.

Alternatively, the segments 20, 60 could be grasped at their proximal ends 28, 68 through an appropriate attachment mechanism inboard of the top and bottom surfaces and lateral surfaces of the segments 20, 60 so that the tongs 90 or other placement tool would not add to a cross-sectional diameter needed for the cannula through which the segments 20, 60 would be passed.

With particular reference to Figures 16 and 17, details of an alternative offset hinge 102 are described. Such an offset hinge 102 is shown on a first alternative primary segment 100. However, the offset hinge 102 could similarly be located on a secondary segment such as a modification of the secondary segment 60 (Figures 11-14). The offset hinge 102 advantageously allows a single pintle to pass through all leaves of the offset hinge 102 (Figure 17). The offset hinge 102 thus avoids the necessity of two partial pintles on opposite sides of a passage 40 (Figure 8) or bore 80 (Figure 13). Otherwise, the alternative primary segment 100 of Figures 16 and 17 is similar to the primary segment 20 of the preferred embodiment of the implant assembly 10 of this invention.

Figure 18 shows a second alternative primary segment 110 featuring a split hinge 112. This split hinge 112 on the second alternative primary segment 110 is generally similar to the hinge 25 of the primary segment 20 of the preferred embodiment (Figure 8). However, the overlapping leaves place the pintles of the split hinge 112 in a slightly different position. The second alternative primary segment 110 and split hinge 112 of Figure 8 illustrate one of the many different hinge configurations which the segments 20, 60 of the implant assembly 10 of this invention can have to effectively allow top and bottom portions of the segments 20, 60 to move relative to each other.

While the material forming the segments 20, 60 would typically be some form of surgical grade bio-compatible stainless steel or other material, it is conceivable that the material forming the segments 20, 60 could be a form of hydrocarbon polymer or other plastic material, or a metallic material which has some appreciable flexibility characteristics. If the segments 20, 60 are made from such materials or can be machined to have sufficiently thin connection between the top and bottom portions of the segments 20, 60, the hinges 25, 102, 112 of the various embodiments of this invention could be replaced with the top and bottom portions of the segments 20, 60 merely flexing relative to each other sufficiently to allow the height expansion at the distal ends 26, 66 of the segments 20, 60 so that an appropriate amount of lordosis can be provided to the intervertebral space S (Figure 1).

With particular reference to Figures 19-21 details of a third alternative primary segment are described. This third alternative primary segment 120 features an offset hinge 122 similar to the offset hinge 102 of the first alternative primary segment 100 (Figure 16). The third alternative primary segment 120 additionally includes undulating overlapping tapering surfaces 124 for portions of the top and bottom structures of the third alternative primary segment 120 adjacent the distal end. These undulating overlapping tapering surfaces 124 can be spread apart by longitudinal advancement of a first alternative shim 126 which is preferably cylindrical and as wide as the entire segment 120. As the first alternative shim 126 is advanced (along arrow P of Figure 19) it passes through a series of steps corresponding with different stages of lordosis which can be provided to the intervertebral space S (Figure 1).

Because the tapering surfaces 124 undulate, a series of locations are provided where the first alternative shim 126 can come to rest. Varying degrees of height adjustment corresponding to various different degrees of lordosis can thus be provided to the intervertebral space S (Figure 1). The first alternative shim 126 can be advanced by being pushed along through an access passage 128 with any appropriate form of pushing tool, or could be advanced with a threaded pin similar to the advancement of the wedge 86 along the pin 82 of the secondary segment 60 of the preferred embodiment.

Because the tapering surfaces 124 overlap, a greater amount of height increase at the distal end of the third alternative primary segment 120 is provided (see Figure 20). This third alternative primary segment 120 height magnification system could be fitted on an alternative secondary segment having a neck rather than a tunnel in a relatively straightforward fashion due to the relatively low profile passage 128 which could pass through a neck without compromising a strength of the neck in such an alternative secondary segment. Hence, this height magnification system is merely illustrated in the context of primary segment for convenience, but could be equally well incorporated into a secondary segment.

With particular reference to Figures 22-27, details of a fourth alternative primary segment are described. The fourth alternative primary segment 130 is configured to allow height adjustment both at a distal end of the fourth alternative primary segment 130 and at a proximal end of the fourth alternative primary segment 130. Specifically, the top and bottom portions of the fourth alternative primary segment 130 are preferably joined together with an expanding hinge 132.

Function of the expanding hinge is shown in detail in Figures 24-27. The expanding hinge 132 includes two separate pintles 134 on opposite sides of a longitudinal passage extending through the fourth alternative primary segment 130. The pintles 134 reside within slots 136. Hence, the expanding hinge 132 allows both rotation and vertical expansion (along arrow R of Figures 25 and 26) while still holding the top and bottom portions of the fourth alternative primary segment 130 together.

A longitudinal passage passing through the fourth alternative primary segment includes a proximal recess 140 near a proximal end of the fourth alternative primary segment 130. A

proximal shim 142 can be advanced along a guide wire in a manner similar to the advancement of the shim 50 of the primary segment 20 of the preferred embodiment. The proximal shim 142 is preferably configured with a contour matching that of the proximal recess 140. Hence, as the proximal shim 142 is advanced into the passage (along arrow Q of Figure 22), the proximal shim
5 142 expands the top and bottom portions of the fourth alternative primary segment 130 away from each other until the proximal shim 142 rests within the proximal recess 140.

As an alternative to providing the proximal recess 140, the proximal shim 142 could merely have a tapering contour (shown in Figure 22) and the friction between tapering surfaces of the proximal shim 142 and upper and lower surfaces of the pathway within the fourth alternative primary
10 segment 130 could allow the proximal shim 142 to remain in a position where it has been advanced unless specific forces are applied to the proximal shim 142.

As shown in Figure 22, a shim similar to the shim 50 of the preferred embodiment would first be advanced along the guide wire into the tapering end of the passage within the fourth alternative primary segment 130. The proximal shim 142 would then be advanced into the passageway.
15 Hence, the fourth alternative primary segment 130 experiences height magnification both adjacent a distal end and adjacent the proximal end of the fourth alternative primary segment 130. The proximal shim 142 could similarly be used with an expanding hinge 132 fitted into the proximal second end 68 of the secondary segment 60 to give the secondary segment 60 proximal end 68 height adjustability.

Figure 28 shows a fifth alternative primary segment 150 which uniquely includes beveled tunnel sides 152. These beveled tunnel sides 152 allow a second alternative secondary segment 155 to pass through the tunnel in a non-perpendicular direction. Specifically, the secondary segment 155 can be angled relative to the fifth alternative primary segment 150 by an angular amount (arrow X
20 of Figure 28) which can be less than or greater than 90°, rather than only exactly 90°. Angle X in Figure 8 is shown at approximately 60° but could be reduced to as little as 45° or less and still allow the secondary segment 155 to pass through the tunnel in the fifth alternative primary segment 150 without being blocked by the beveled tunnel sides 152. The beveled tunnel sides 152 are shown angled approximately 45° away from an orientation perpendicular to a long axis of the fifth alternative primary segment 150. However, the angles of the beveled tunnel sides 152 and the angle
25 X that the secondary segment 155 shares relative to the fifth alternative primary segment 150 could be increased or decreased depending on the needs of the medical practitioner for the implant assembly 10.

The second alternative secondary segment 155 preferably includes a relief bevel 156 (Figure 28) which allows a side wall of the neck in the second alternative secondary segment 155 to come into
35 contact with a side surface of the first alternative primary segment 150 after the second alternative secondary segment 155 has been rotated into its final position. The relief bevel 156 thus allows the second alternative secondary segment 155 and the fifth alternative primary segment 150 to more completely stabilize each other in a fully interlocking fashion so that the implant assembly 10

stabilizes the intervertebral space S (Figure 1) as completely as needed.

A sixth alternative primary segment 160 is shown in Figure 29 which includes relief notches 162 in sides of the sixth alternative primary segment 160 adjacent the tunnel. The relief notches 162 are an alternative to the relief bevel 156 of the embodiment of Figure 28. Specifically, Figure 29 illustrates how either the relief bevel 156 can be provided on the second alternative secondary segment 155 or relief notches 162 can be provided as in the sixth alternative primary segment 160 so that complete rotation of the third alternative secondary segment 164 can be achieved without the necessity of the relief bevel 156 of the second alternative secondary segment 155. Of course a combination of the relief bevel 156 and the relief notches 162 could be resorted to so that abutting surfaces of the primary segment and the secondary segment could mesh together in a manner providing stability for the overall implant assembly 10.

A fourth alternative secondary segment 170 is shown in Figure 30 along with the fifth alternative primary segment 150. This implant assembly shown in Figure 30 is shown with the first alternative primary segment 150 in section and clearly illustrating how the fourth alternative secondary segment 170 can fit through the tunnel in the fifth alternative primary segment 150 at an angle X (Figure 28) other than perpendicular and be rotated, about arrow T, and to the final position such as that shown in Figure 28.

It can be seen from Figure 30 that not all of the beveled tunnel sides 152 are strictly necessary for the passage of the fourth alternative secondary segment 170 through the tunnel in the fifth alternative primary segment 150. By providing the beveled tunnel sides 152 in two directions, the fifth alternative primary segment 150 becomes reversible. However, inclusion of both beveled tunnel sides 152 would not be absolutely necessary. Rather, only one beveled tunnel side 152 could be provided on each side of the tunnel and other beveled tunnel sides 152 could be eliminated. Particularly, and as shown in Figure 30, the beveled tunnel sides 152 which include reference numerals thereon could be removed and the fourth alternative secondary segment 170 could still pass through the tunnel in the fifth alternative primary segment 150 successfully.

Selective relief bevels 172 similar to the relief bevels 156 (Figure 28) could be provided on some of the neck side walls, but would not need to be on all neck side walls. The selective relief bevels 172 would come to rest adjacent sides of the primary segment 150 after rotation about arrow T and provide enhanced stability between the segments 150, 170.

This disclosure is provided to reveal a preferred embodiment of the invention and a best mode for practicing the invention. Having thus described the invention in this way, it should be apparent that various different modifications can be made to the preferred embodiment without departing from the scope and spirit of this disclosure. For instance, while the primary segment 20 and the secondary segment 60 are described in the preferred embodiment as being expandable, a simplified variation of this invention would not require such expandability. When structures are identified as a means to perform a function, the identification is intended to include all structures which can perform the function specified.

Industrial Applicability

This invention exhibits industrial applicability in that it provides an implant for an intervertebral space which can be implanted posteriorly and still provide a substantially rigid implant assembly for spreading and stabilization of the vertebrae adjacent the intervertebral space.

Another object of the present invention is to provide an implant assembly having separate segments which are as low profile as possible so that posterior implantation can be accomplished in as minimally invasive a surgical procedure as possible.

Another object of the present invention is to provide an implant assembly for an intervertebral space which is initially entered into the intervertebral space in separate segments which are later interlocked together.

Another object of the present invention is to provide an intervertebral space implant assembly which can be adjusted in height to maximize a size of the intervertebral space generally and to allow for selective height adjustment within different portions of the intervertebral space, to provide a surgeon with a maximum amount of flexibility in positioning vertebrae adjacent the intervertebral space as precisely as desired.

Another object of the present invention is to provide an implant assembly which can be located within an intervertebral space with little risk of damage to sensitive surrounding tissues.

Other further objects of this invention, which demonstrate its industrial applicability, will become apparent from a careful reading of the included detailed description, from a review of the enclosed drawings and from review of the claims included herein.

CLAIMS

What is claimed is:

- 5 Claim 1 - An implant for surgical placement within an intervertebral space, such as during a spinal fusion procedure, the implant comprising in combination:
- a primary segment having an elongate form between a distal end and a proximal end;
 - a secondary segment having an elongate form between a first end and a second end; and
 - a portion of said secondary segment between said first end and said second end crossing
- 10 said primary segment between said distal end and said proximal end.

- Claim 2 - The implant of Claim 1 wherein both said primary segment and said secondary segment have a height between a top surface and a bottom surface which is greater than a width between lateral sides of said segments, such that rotation of said segments about a long axis from
- 15 an orientation where said top surface is laterally spaced from said bottom surface to an orientation where said top surface is above said bottom surface results in an increase in height of both said segments.

- Claim 3 - The implant of Claim 1 wherein at least a portion of at least one of said segments is
- 20 open sufficiently to allow the other of said segments to pass at least partially through said open portion, such that said segments are at least partially interlocking together.

- Claim 4 - The implant of Claim 3 wherein said open portion is sufficiently large that said segments are substantially coplanar.

- 25 Claim 5 - The implant of Claim 4 wherein a height of said primary segment between a top surface and a bottom surface is equal to a height of said secondary segment between a top surface and a bottom surface with said top surface of said primary segment coplanar with said top surface of said secondary segment and said bottom surface of said primary segment coplanar with said
- 30 bottom surface of said secondary segment.

- Claim 6 - The implant of Claim 3 wherein said primary segment is at least partially open between said distal end and said proximal end and said secondary segment is at least partially open between said first end and said second end, said opening in said primary segment adjacent said
- 35 opening in said secondary segment where said secondary segment crosses said primary segment, such that said primary segment and said secondary segment are at least partially interlocking together.

Claim 7 - The implant of Claim 6 wherein said opening in said primary segment is a tunnel between a top surface and a bottom surface, said tunnel at least as large as at least a portion of said secondary segment between said first end and said second end, such that said second segment can be located extending through said tunnel.

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Claim 8 - The implant of Claim 7 wherein said secondary segment includes a neck between said first end and said second end, said neck having a lesser height between a top surface of said secondary segment and a bottom surface of said secondary segment than a height of other portions of said secondary segment adjacent said neck, said neck having a height less than a height of said tunnel in said primary segment, such that said neck of said secondary segment can be located extending through said tunnel in said primary segment.

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Claim 9 - The implant of Claim 1 wherein said primary segment includes a top structure and a bottom structure, said top structure and said bottom structure movable relative to each other, such that a height of said primary segment can be modified.

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Claim 10 - The implant of Claim 9 wherein said primary segment includes a spacer between said top structure and said bottom structure, said spacer moving said top structure away from said bottom structure to increase a height of said primary segment.

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Claim 11 - The implant of Claim 10 wherein said spacer is a shim having a tip with a lesser height than a tail, said primary segment including a passage extending at least partially through said primary segment between said top structure and said bottom structure, said passage having a lesser height in a tapering region, said tapering region closer to said distal end than to said proximal end, said shim having a height greater than a height of said passage at said tapering region, such that said shim pushes said top structure away from said bottom structure when said shim is moved through said passage into said tapering region.

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Claim 12 - The implant of Claim 9 wherein said top structure and said bottom structure are hinged together at a location on said primary segment closer to said proximal end than to said distal end.

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Claim 13 - The implant of Claim 12 wherein said second segment includes a top jaw and a bottom jaw, said top jaw movable relative to said bottom jaw, said top jaw and said bottom jaw hinged together at a location closer to said second end of said secondary segment than said first end of said secondary segment.

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Claim 14 - The implant of Claim 13 wherein said hinge in said primary segment and said hinge in said secondary segment are each expansion hinges which allow both pivoting and vertical translation of portions of said structures adjacent said hinge.

5 Claim 15 - An implant for an intervertebral space, the implant comprising in combination:
 a primary segment having an elongate form between a distal end and a proximal end;
 a second segment having an elongate form between a first end and a second end;
 a portion of said second segment between said first end and said second end intersecting
said primary segment between said distal end and said proximal end;
10 said primary segment including a tunnel passing laterally therethrough between said distal
end and said proximal end;
 said tunnel having a height less than a height of said primary segment;
 said secondary segment including a neck between said first end of said secondary segment
and said second end of said secondary segment;
15 said neck having a height less than portions of said secondary segment adjacent said neck;
and
 said neck having a height at least as small as a height of said tunnel in said primary
segment, such that said neck in said secondary segment can be located extending through said
tunnel in said primary segment.

20 Claim 16 - The implant of Claim 15 wherein said neck of said secondary segment is sized to
allow said secondary segment to rotate at least 90° about a long axis of said secondary segment
while said neck of said secondary segment is within said tunnel in said primary segment.

25 Claim 17 - The implant of Claim 16 wherein said primary segment includes a top structure and
a bottom structure, said top structure hingedly attached to said bottom structure at a location closer
to said proximal end than to said distal end, and said secondary structure having a top jaw hingedly
attached to a bottom jaw at a location on said secondary segment closer to said second end than to
said first end.

30 Claim 18 - An intervertebral space implant comprising in combination:
 a primary segment having an elongate form between a distal end and a proximal end;
 a second segment having an elongate form between a first end and a second end;
 a portion of said second segment between said first end and said second end crossing said
35 primary segment between said distal end and said proximal end; and
 at least one of said segments at least partially open at a location between ends thereof, such
that said primary segment and said secondary segment are at least partially interlocking where said
segments cross.

Claim 19 - The implant of Claim 18 wherein both said primary segment and said secondary segment include an at least partially open region between ends thereof.

Claim 20 - The implant of Claim 18 wherein said primary segment includes a tunnel passing
5 laterally therethrough between said distal end and said proximal end, said secondary segment including a neck between said first end and said second end, said neck in said secondary segment sized sufficiently small to pass through said tunnel in said primary segment.

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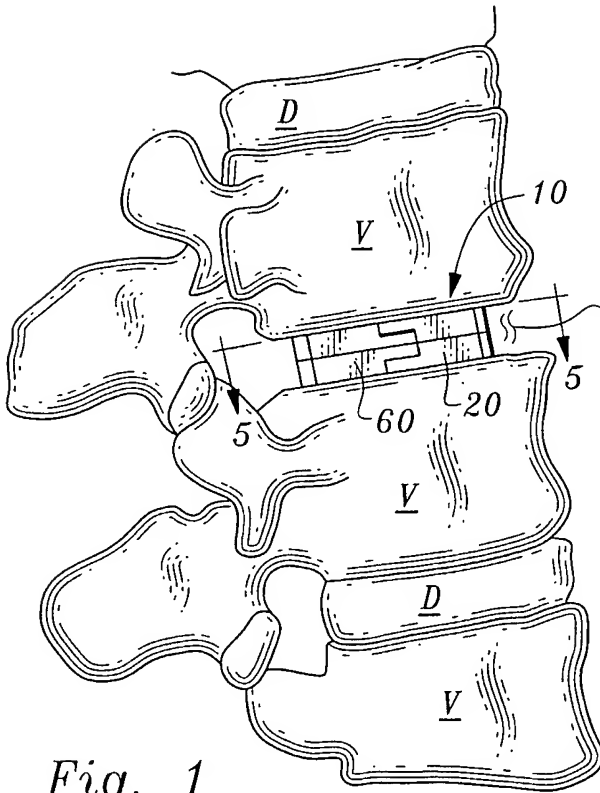


Fig. 1

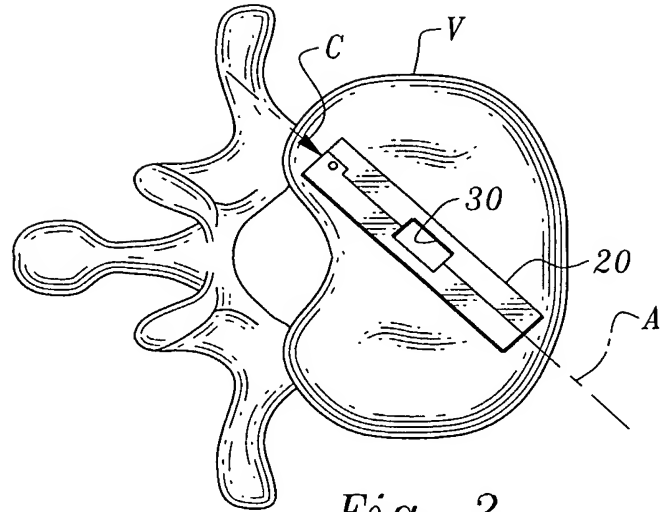


Fig. 2

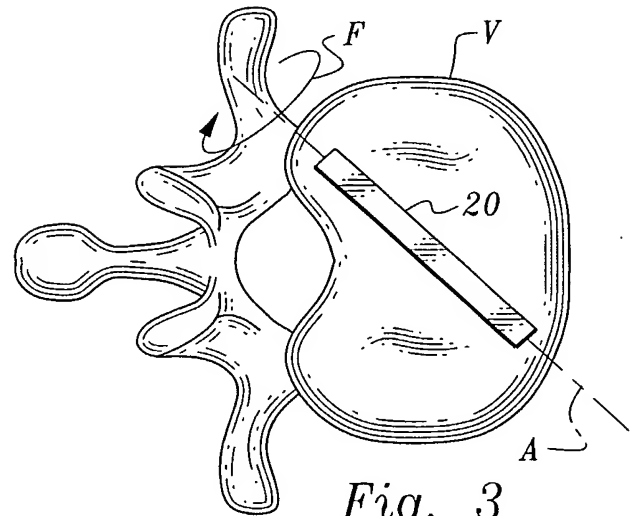


Fig. 3

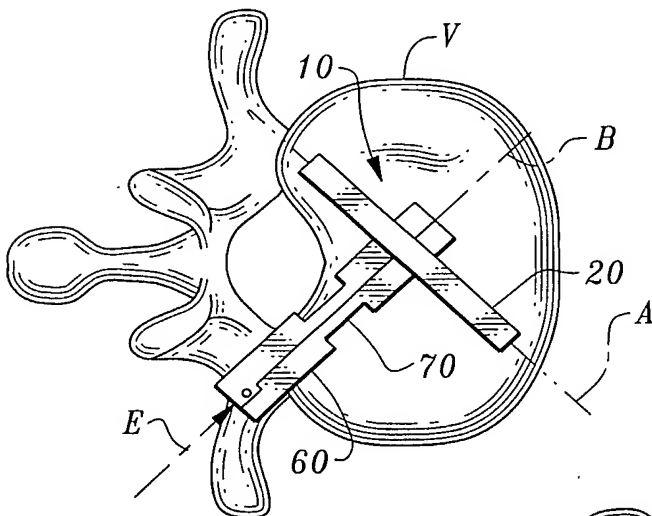


Fig. 4

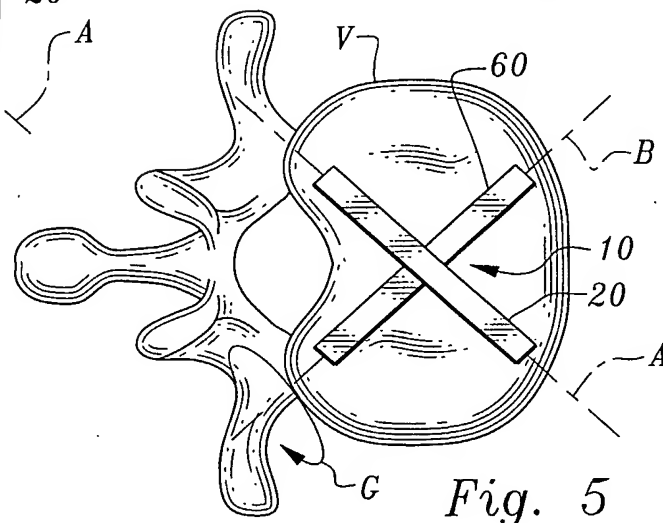


Fig. 5

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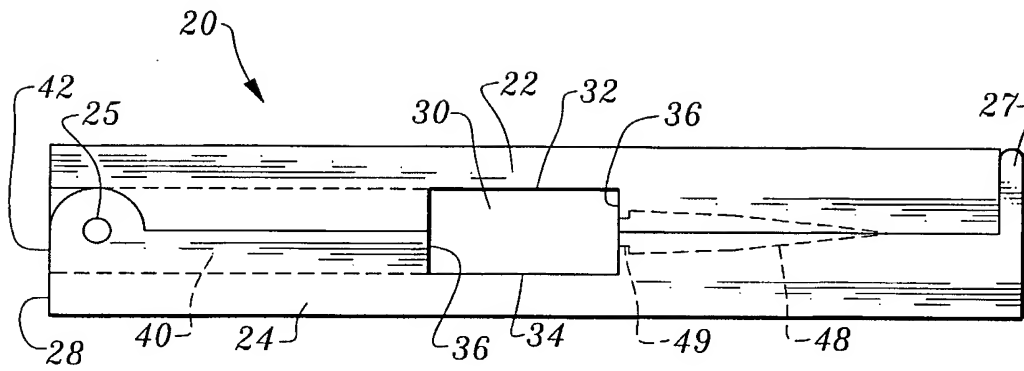


Fig. 6

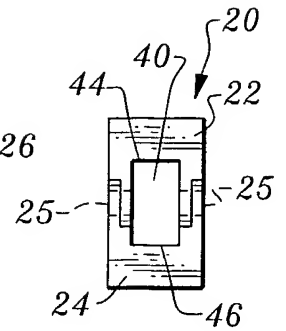


Fig. 8

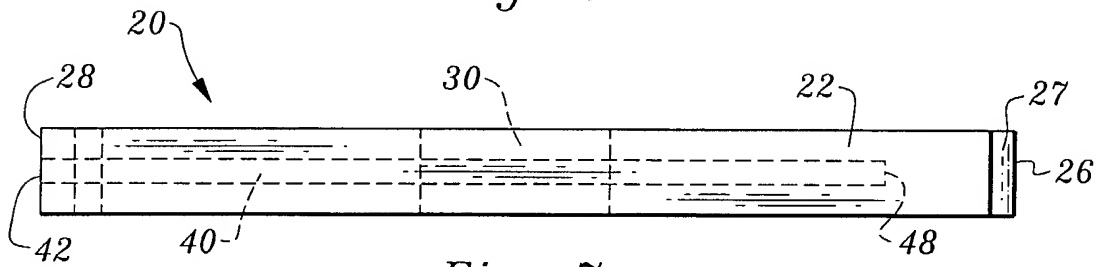


Fig. 7

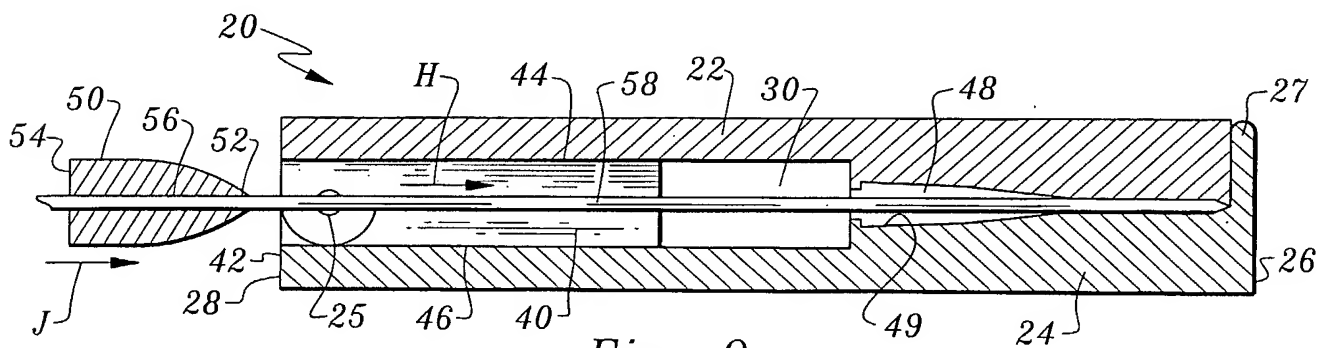


Fig. 9

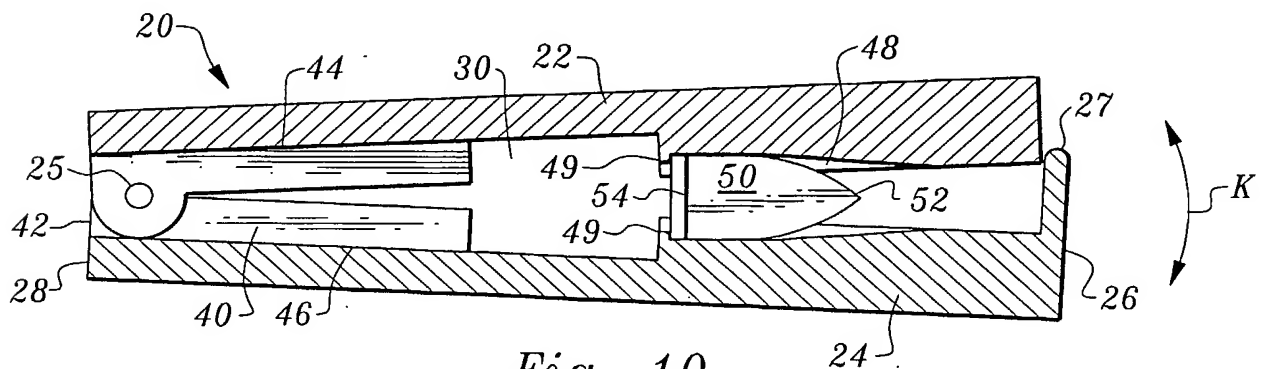


Fig. 10

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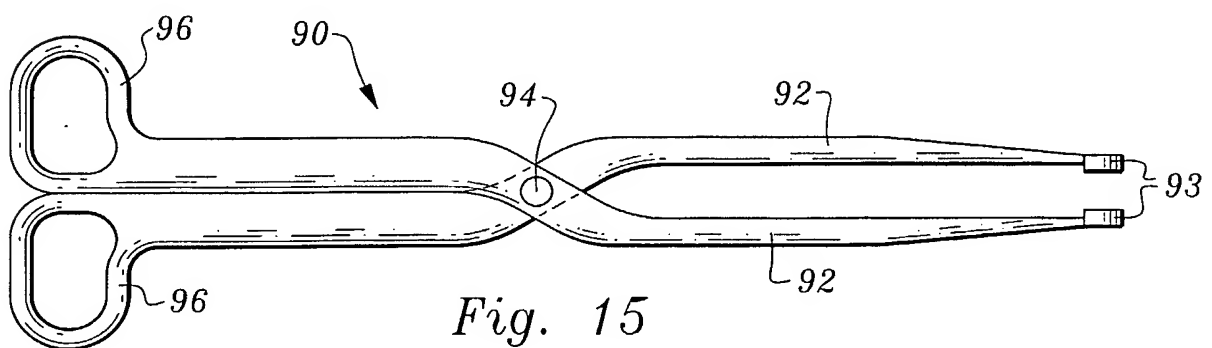
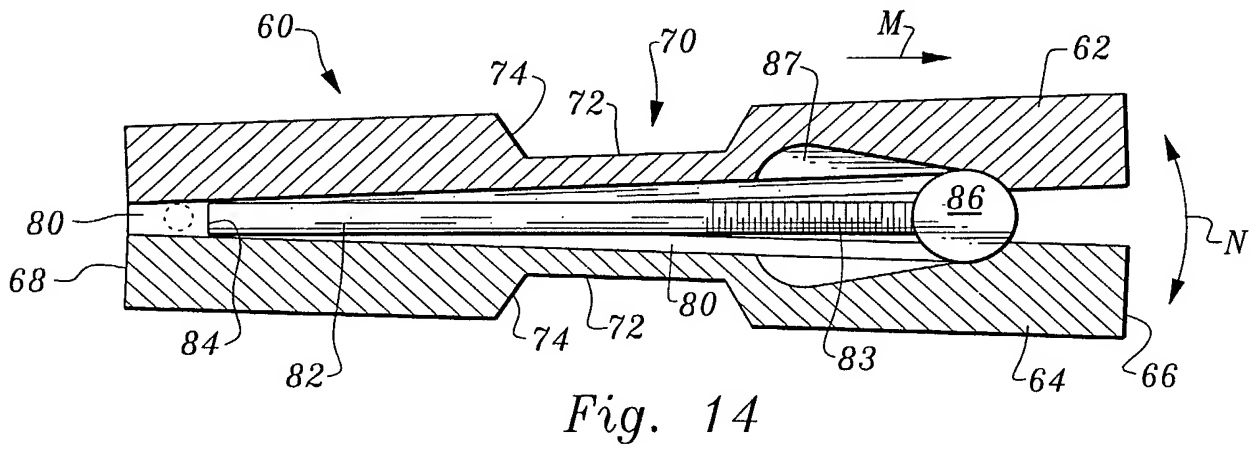
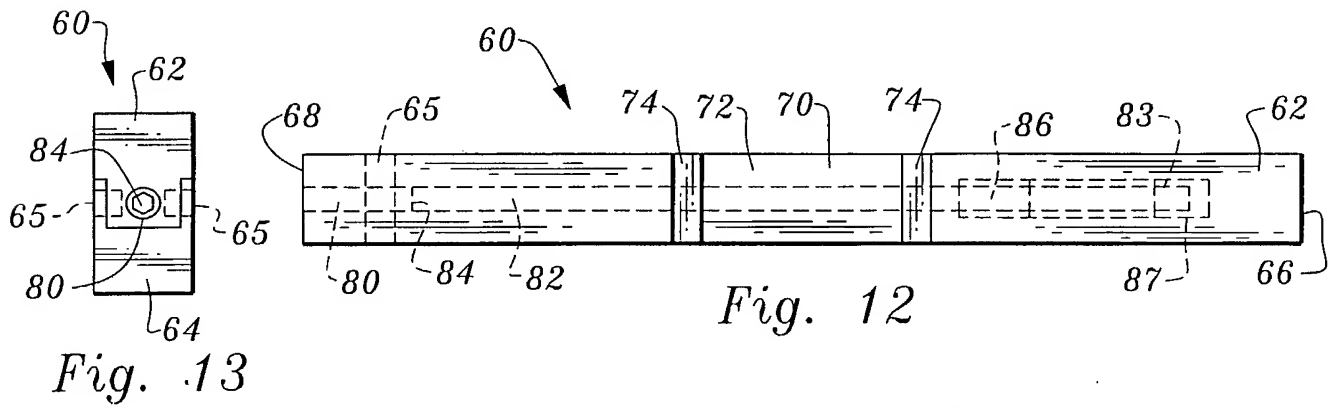
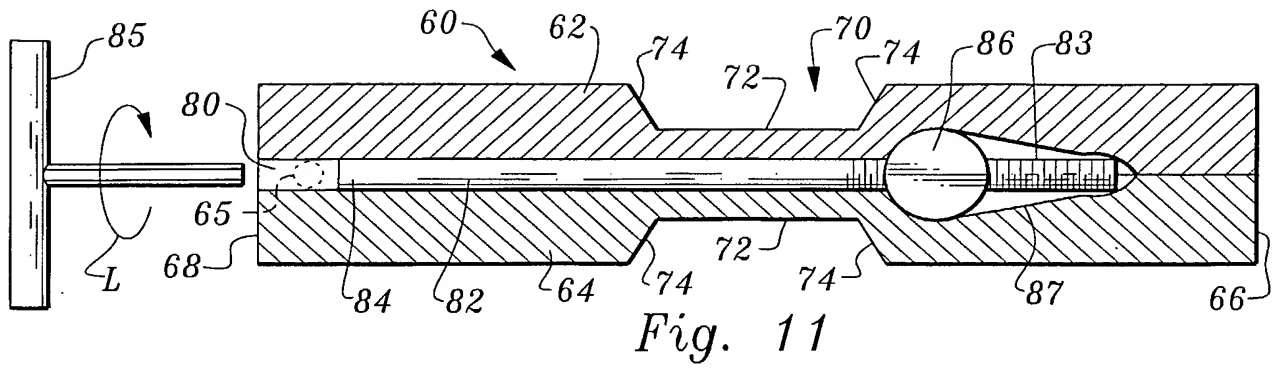


Fig. 15

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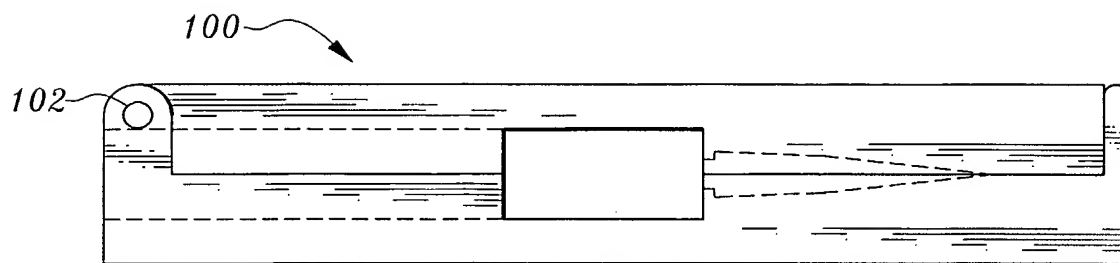


Fig. 16

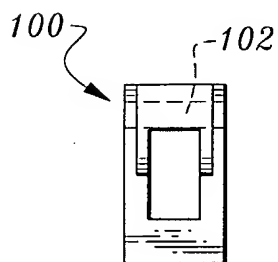


Fig. 17

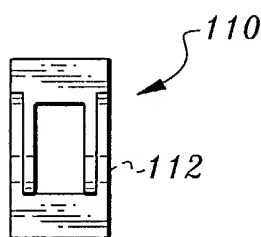


Fig. 18

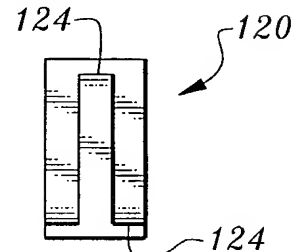


Fig. 20

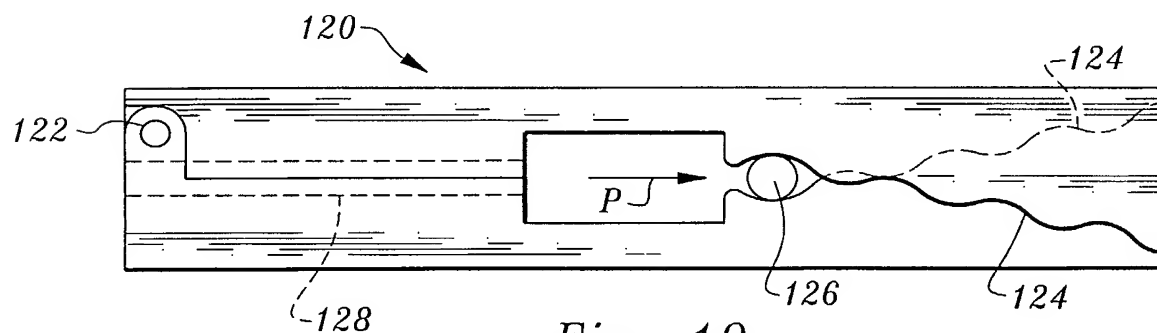


Fig. 19

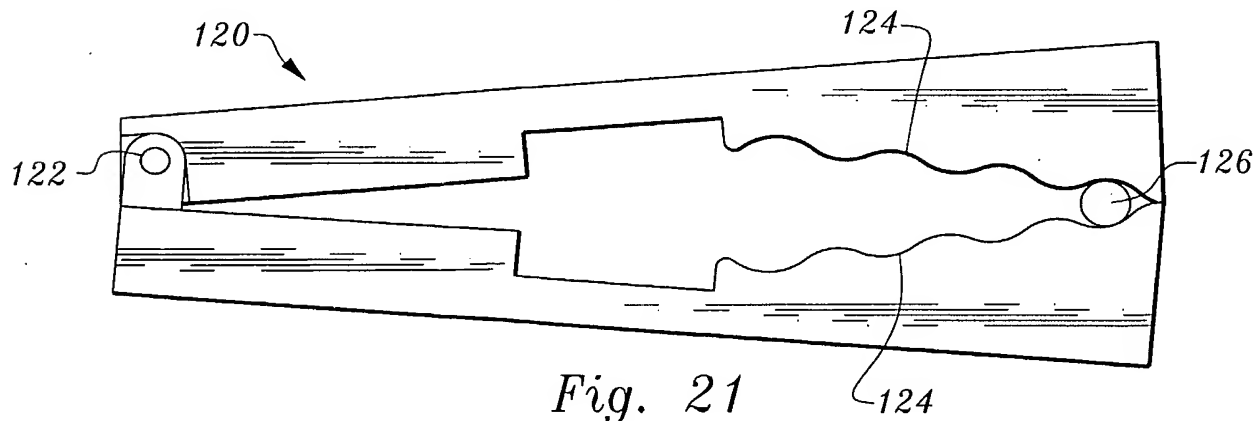


Fig. 21

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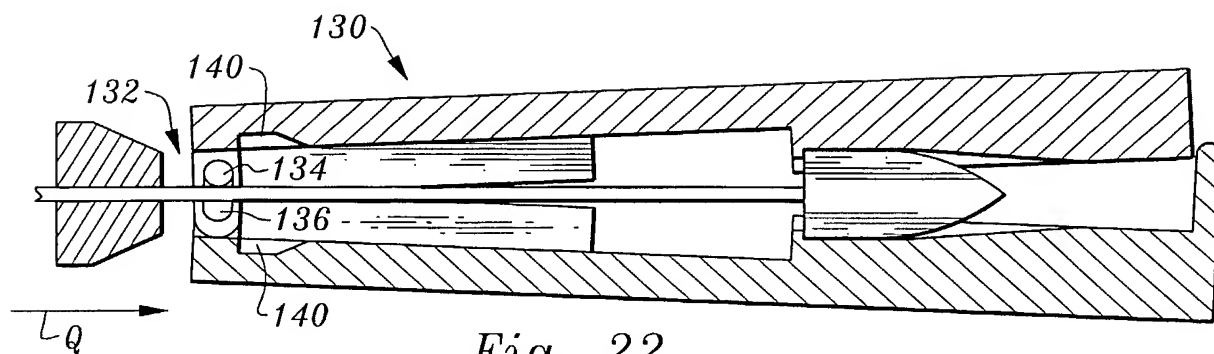


Fig. 22

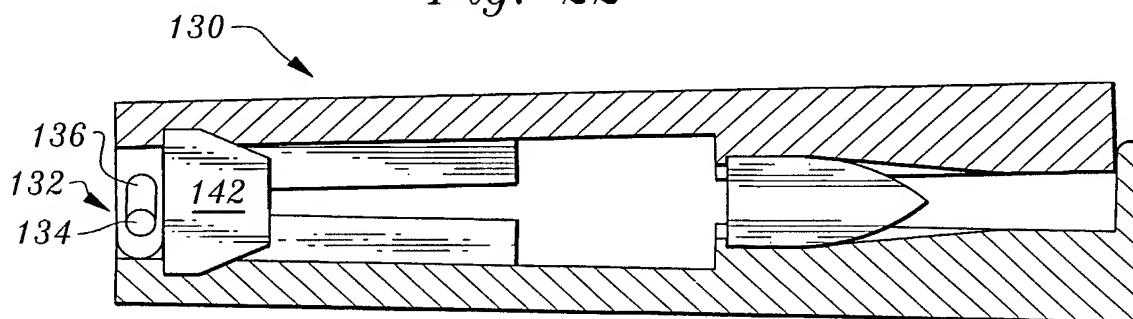


Fig. 23

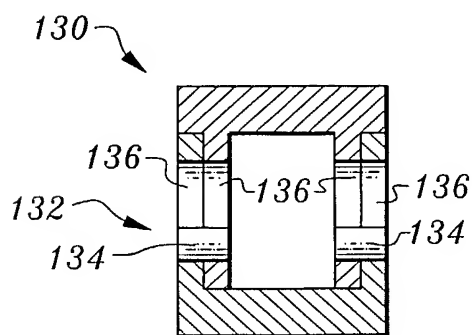


Fig. 24

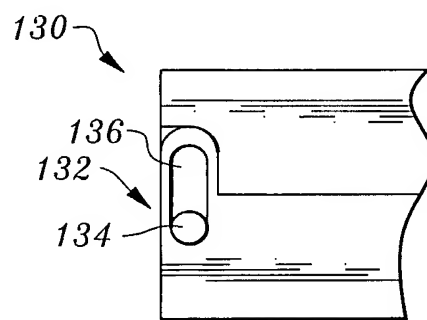


Fig. 26

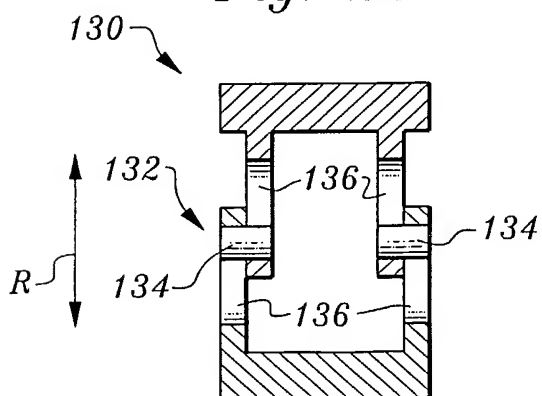


Fig. 25

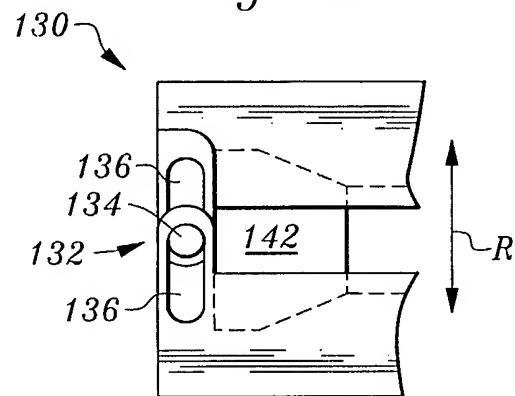


Fig. 27

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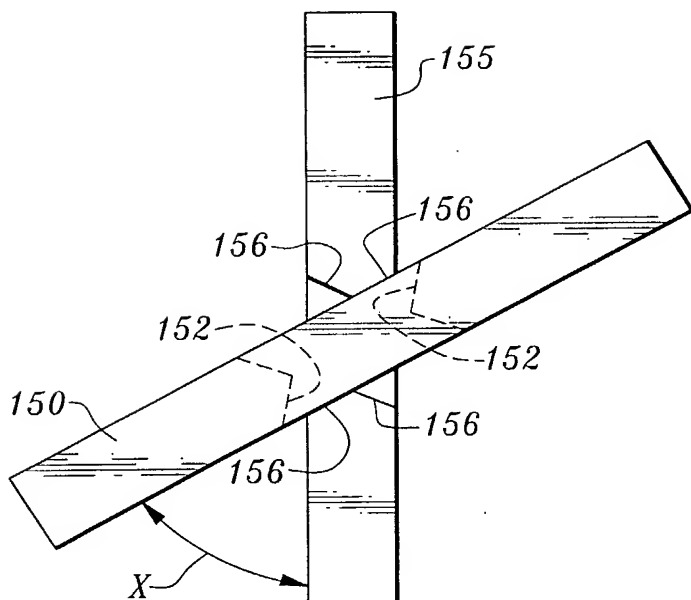


Fig. 28

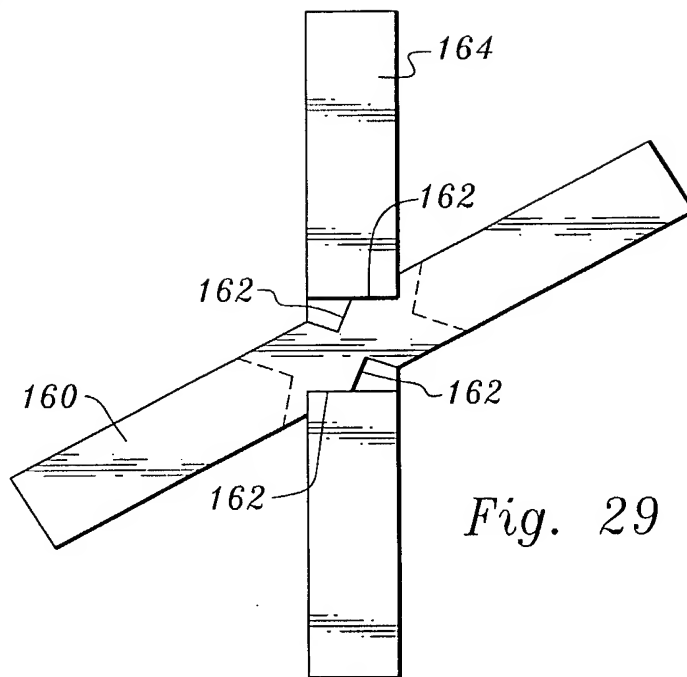


Fig. 29

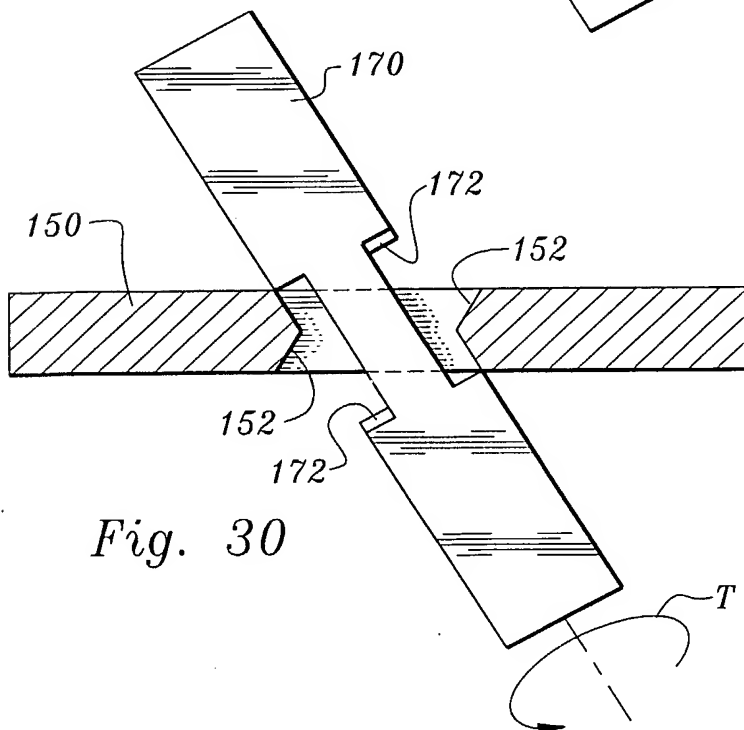


Fig. 30

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/08845**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61F 2/44

US CL :623/17.15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.15,17.11,17.13, 17.16; 606/53,60,61,69,70,71

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,	Us 6,190,414 B1 (Young et al) 20 February 2001, see entire document	1-20
A	US 6,193,757 B1 (Foley et al) 27 February 2001, see entire document	1-20
A	US 5,989,291 A (Ralph et al.) 23 November 1999, see entire document	1-20
A	US 6,045,579 A (Hochshuler et al.) 4 April 2000, see entire document	1-20
A	US 6,162,252 A (Kuras et al.) 19 December 2000, see entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:		"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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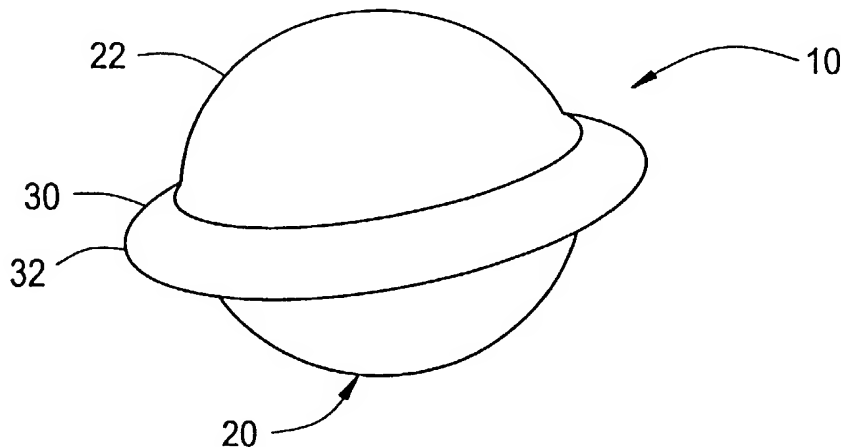
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(54) Title: SPHERICAL SPINAL IMPLANT



(57) **Abstract:** An improved prosthetic implant for forming a support between adjoining vertebrae in a spinal column. The prosthetic implant includes a generally spherical or ellipsoidal body that at least partially engages a surface of an adjacent vertebrae. The generally spherical or ellipsoidal body can include an opening to receive packing material such as medicine, human tissue and the like. The generally spherical or ellipsoidal body can include a stabilizer to at least partially limit the movement of the prosthetic implant between two vertebrae.



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SPHERICAL SPINAL IMPLANT

This application claims priority on co-pending United States Provisional Application Serial No. 60/277,038, filed March 30, 2001, entitled "Spherical Spinal Implant."

5 The present invention pertains to prosthetic implants, and more particularly to inner body spinal prosthetic implants to fuse two or more vertebrae together, and even more particularly to inner body spinal prosthetic implants that provide a substitute for an intervertebral disc and/or that provide a flexible spacer between two vertebrae.

INCORPORATION BY REFERENCE

10 United States Provisional Application Serial No., filed, entitled "Spherical Spinal Implant" is incorporated by reference. Also incorporated herein by reference is United States Patent Application Serial No. 09/494,645, filed January 31, 2000 entitled "Spinal Fusion Implant."

BACKGROUND OF THE INVENTION

15 The human spine is made up of a column of thirty-three bones and their adjoining structures. The vertebrae near the head are known as the presacral vertebrae which are separate bones capable of individual movement. The bodies of these vertebrae are connected by anterior and posterior ligaments and by discs of fibrocartilage generally known as intervertebral discs. These discs are positioned between opposite faces of adjacent vertebral bodies. This column of vertebrae and intervertebral discs form a central axis that supports the head and torso. These
20 vertebrae also enclose an opening through which the spinal cord passes therebetween.

The presacral vertebrae are normally held in position to one another by the intervertebral discs, ligaments and musculature of the body. These vertebrae move relative to adjacent vertebrae thus permitting the head to be turned relative the body and providing a wide range of flexibility to the spine.

25 One of the most costly health problems in society involves back pain and pathology of the spine. These problems can affect individuals of all ages and can result in great suffering to victims. Back pain can be caused by several factors such as congenital deformities, traumatic injuries, degenerative changes to the spine, and the like. Such changes can cause painful excessive motion, or collapse of a motion segment resulting in the contraction of the spinal canal
30 and compressing the neural structures causing debilitating pain, paralysis or both, which in turn

can result in nerve root compression or spinal stenosis.

Nerve conduction disorders can also be associated with intervertebral discs or the vertebrae themselves. One such condition is herniation of the intervertebral disc, in which a small amount of tissue protrudes from the sides of the disc into the foramen to compress the spinal cord. A second common condition involves the development of small bone spurs, termed osteophytes, along the posterior surface of the vertebral body, again impinging on the spinal cord.

Upon identification of these abnormalities, surgery may be required to correct the problem. For those problems associated with the formation of osteophytes or herniations of the intervertebral disc, one such surgical procedure is intervertebral discectomy. In this procedure, the involved vertebrae are exposed and the intervertebral disc is removed, thus removing the offending tissue or providing access for the removal of the bone osteophytes. A second procedure, termed a spinal fusion, may then be required to fix the vertebrae together to prevent movement and maintain a space originally occupied by the intervertebral disc. Although this procedure may result in some minor loss and flexibility in the spine, due to the relatively large number of vertebrae, the minor loss of mobility is typically acceptable.

During a spinal fusion following a discectomy, a prosthetic implant or spinal implant is inserted into the intervertebral space. This prosthetic implant is often a bone graft removed from another portion of the patient's body, termed an autograph. The use of bone taken from the patient's body has the important advantage of avoiding rejection of the implant, but has several shortcomings. There is always a risk in opening a second surgical site in obtaining the implant, which can lead to infection or pain for the patient, and the site of the implant is weakened by the removal of bony material. The bone implant may not be perfectly shaped and placed, leading to slippage or absorption of the implant or failure of the implant to fuse with the vertebrae.

Other options for a graft source of the implant are bone removed from cadavers, termed allograft, or from other species, termed a xenograft. In these cases, while there is the benefit of not having a second surgical site as a possible source of infection or pain, there is increased difficulty of the graft rejection and the risk of transmitting communicable diseases.

An alternative approach is using a bone graft or using a manufactured implant made of a synthetic material that is biologically compatible with the body and the vertebrae. Several

compositions and geometries of such implants have been utilized, ranging from simple blocks of material to carefully shaped implants, with varying success.

There has been an extensive number of attempts in developing an acceptable prosthetic implant that can be used to replace an intervertebral disc and yet maintain the stability of the intervertebral disc spaced between adjacent vertebrae, at least until complete arthrodesis is achieved. These prosthetic implants have taken many forms. While many types of synthetic prosthetic devices have been proposed, the success ratio has been low and the surgical procedures have been complicated and often traumatic to the patient.

One of the more prevailing designs of these prosthetic implants takes the form of a cylindrical implant. These types of prosthetic implants are represented by Brantigan 4,878,915 and Ray 4,961,740. In these cylindrical implants, the exterior portion of the cylinder can be threaded to facilitate insertion of the prosthetic device. Some of these prosthetic implants are designed to be pounded into the intervertebral disc space and the vertebral end plates. These types of devices are represented in Brantigan 4,834,757 and Brantigan 5,192,327. The Brantigan and Ray patents all disclose prosthetic implants wherein the transverse cross-section of the implant is constant throughout the length of the implant and is typically in the form of a right circular cylinder.

Other prosthetic implants have been developed that do not have a constant cross-section. For instance, the patent to McKinna 4,714,469 shows a hemispherical implant with elongated protuberances that project into the vertebral end plate. The implant of Bagby 4,934,848 is in the form of a sphere which is positioned between the centrums of the adjacent vertebrae.

The various prosthetic implants can be generally divided into two basic categories, namely solid implants and implants designed to encourage bone ingrowth. Solid implants are represented by United States Patent Nos. 4,878,915 and 4,349,921. The remaining patents discussed above include some aspect that permits bone to grow across the implant. It has been found that devices which promote natural bone ingrowth achieve a more rapid and stable arthrodesis. These implants are typically filled with autologous bone prior to insertion into the intervertebral disc space. These implants typically include apertures which communicate with openings in the implant, thereby providing a path for tissue growth between the vertebral end plate and the bone or bone substitute within the implant. In preparing the intervertebral disc

space for a prosthetic implant, the end plates of the vertebrae are preferably reduced to bleeding bone to facilitate tissue growth within the implant.

A number of difficulties still remain with the many prosthetic implants currently available. While it is recognized that hollow implants which permit bone ingrowth in the bone or bone substitute within the implant is an optimum technique for achieving fusion, most of these devices have difficulty achieving this fusion, at least without the aid of some additional stabilizing device, such as a rod or plate. Moreover, some of these devices are not structurally strong enough to support the heavy loads applied at the most frequently fused vertebral levels, mainly those in the lower lumbar spine.

In view of the present state of technology related to prosthetic implants, there is a continued need for new implant designs that optimize the bone ingrowth capabilities and are strong enough to support the vertebrae until arthrodesis occurs, maintains or restores the normal spinal anatomy at the instrumented segment, and/or exhibits reduced slippage when inserted between vertebrae and diminishes the occurrence of nerve pinching.

SUMMARY OF THE INVENTION

The present invention pertains to an improved implant, and more particularly to an improved prosthetic implant for insertion between one or more vertebrae and a method for inserting the prosthetic implant between one or more vertebrae.

In accordance with the principal feature of the present invention, there is provided a prosthetic implant that is formed of a biologically compatible material for use in humans. The prosthetic implant is shaped and sized for insertion between two vertebrae. In one specific embodiment, the prosthetic implant is designed to be placed in the intervertebral disc space that was formerly occupied by at least a portion of an intervertebral disc. The intervertebral disc is partially or completely removed prior to insertion of the prosthetic implant between the vertebrae. In another embodiment, the prosthetic implant is designed to be readily inserted by established surgical procedures, with minimal chances of surgical difficulty. In yet another embodiment, the geometry of the prosthetic implant ensures proper load bearing, desired load bearing and support through the vertebrae so as to reduce or minimize the likelihood of the prosthetic implant dislocating relative to the vertebrae either during surgery or during the post operative fusing process. In still another embodiment, the prosthetic implant includes a generally

spherical or ellipsoidal body. The maximum radii of the generally spherical or ellipsoidal body can be varied depending upon the location of the prosthetic implant in the vertebrae. Typically, the maximum radii of the generally spherical or ellipsoidal body will vary from about 3-15mm; however, other radii can be used. In one aspect of this embodiment, the maximum radii of the generally spherical or ellipsoidal body is selected so that the generally spherical or ellipsoidal body can be at least partially positioned between the two adjacently positioned vertebrae and the surrounding fibers and muscle that complete the spinal structure. In one particular aspect, the maximum radii of the generally spherical or ellipsoidal body is selected to cause two adjacently positioned vertebrae to at least partially separate from one another a distance greater than their relative positions prior to surgery. The spreading of the adjacently positioned vertebrae from their original positions results in the elastic nature of the surrounding tissue and muscles maintaining the inserted prosthetic implant in compression between the vertebrae. In another particular aspect, the maximum radii of the generally spherical or ellipsoidal body is selected to cause two adjacently positioned vertebrae to at least partially separate from one another a distance generally equal to or less than their relative positions prior to surgery.

In still yet another embodiment, the prosthetic implant is capable of achieving arthrodesis (fusion) and/or arthroplasty (joint formation) between adjacent vertebrae, depending on the desired procedure. As such, the prosthetic implant allows the surgeon to cause either a multidirectional joint or a fusion to form between two of more vertebrae. In still another embodiment, the prosthetic implant reduces or eliminates nerve pressure caused by a damaged or removed disc.

In accordance with another aspect of the present invention, there is provided a prosthetic implant which includes a generally spherical or ellipsoidal body design to be inserted in a cavity between two adjacent vertebrae. In one embodiment, the prosthetic implant is substantially spherical. In another embodiment, the prosthetic implant is ellipsoidal. In still another embodiment, the prosthetic implant is made of a material that is inert or biologically compatible with the vertebrae and/or surrounding tissue about the vertebrae. The material of the prosthetic implant includes, but is not limited to, bone, stainless steel, titanium, chromemolybdenum, cobalt chromium alloy, ceramic (zirconium oxide ceramic, aluminum oxide ceramic, etc.), chrome or chrome alloys, cobalt or cobalt alloys, polycarbonate, polypropylene, polyethylene,

polymethylmethacrylate, polysulfone types filled with glass and/or carbon fibers, and various types of carbon and fiber reinforced polymers. In one aspect of this embodiment, the material is wear resistant. In another aspect of this embodiment, the material has an increased frictional coefficient. In still another aspect of this embodiment, the material has a reduced frictional coefficient. In accordance with another embodiment, the prosthetic implant is designed to maintain a tension load of about ten to forty pounds, and more preferably about fifteen to thirty-five pounds on the disc tissue and/or vertebral endplate. This tension load facilitates in maintaining the prosthetic implant in position between the vertebrae and accelerates bone ingrowth between the vertebrae, if such bone growth is desired. In still another embodiment, the prosthetic implant is made of a material which closely approximates the elasticity of the vertebrae. In still yet another embodiment, the prosthetic implant is coated with, made up of, and/or contains a material which is radiolucent to enhance the visibility of the implant when exposed to X-rays. In a further embodiment, the prosthetic implant is coated with, made up of, and/or contains a material to enhance the visibility of the implant when exposed to sound waves, light waves, magnetic waves, and/or various types of electromagnetic waves.

In accordance with still another aspect of the present invention, the generally spherical or ellipsoidal body of the prosthetic implant includes a substantially smooth outer surface or includes regions having a substantially smooth outer surface to prevent or substantially prevent bone growth and/or other tissue growth on the substantially smooth surface and/or into the interior of the generally spherical or ellipsoidal body of the prosthetic implant. The substantially smooth surface of the generally spherical or ellipsoidal body allows the generally spherical or ellipsoidal body to move freely or relatively freely between two vertebrae. The growth of bone or other tissue into the generally spherical or ellipsoidal body can result in the generally spherical or ellipsoidal body becoming seized or at least partially retained in a position relative to one or both vertebrae. In one embodiment, the outer smooth surface material of the generally spherical or ellipsoidal body includes a wear resistant, relatively smooth material. The material may also have low frictional characteristics to allow for better movement between one or more vertebrae. In another embodiment, the substantially smooth surface has a total surface area that represents at least the majority of the total surface area of the generally spherical or ellipsoidal body. In one aspect of this embodiment, the substantially smooth surface has a total surface area that

represents at least about 60 percent of the total surface area of the generally spherical or ellipsoidal body. In another aspect of this embodiment, the substantially smooth surface has a total surface area that represents at least about 70 percent of the total surface area of the generally spherical or ellipsoidal body. In yet another aspect of this embodiment, the substantially smooth surface has a total surface area that represents at least about 80 percent of the total surface area of the generally spherical or ellipsoidal body. In still another aspect of this embodiment, the substantially smooth surface has a total surface area that represents at least about 90 percent of the total surface area of the generally spherical or ellipsoidal body. In still yet another aspect of this embodiment, the substantially smooth surface has a total surface area that represents at least about 95 percent of the total surface area of the generally spherical or ellipsoidal body. In still another embodiment, the generally spherical or ellipsoidal body is at least partially coated with a material that reduces or eliminates voids and/or non-smooth surfaces in the outer surface of the generally spherical or ellipsoidal body. In one aspect of this embodiment, the coating is a biocompatible material. Non-limiting materials that can be used include polytetrafluoroethylene, or polymers and/or co-polymers that includes polytetrafluoroethylene. In another embodiment, the coated material can be applied to the generally spherical or ellipsoidal body by adhesive bonding, welding, soldering, shrink wrapping, melting, spray coating, hot dipping, electroplating, immersion coating, brush coating, and/or the like. The coated material can be biologically neutral or include one or more substances that inhibit bone and/or other tissue growth. In one aspect of this embodiment, the coating includes one or more substances that migrate from the coated material into the surrounding tissue. In one specific design, the one or more substances are inserted in, entrapped in and/or at least partially bonded to the coated material so as to at least partially control the time of release and/or release rate of the one or more substances into the surrounding tissue. In another embodiment, the coating material enhances the strength and/or durability of the prosthetic implant and/or hardens or softens the surface of the prosthetic implant.

In accordance with yet another aspect of the present invention, the generally spherical or ellipsoidal body of the prosthetic implant includes one or more smooth surfaces to promote bone growth and/or other tissue growth into the surface of the generally spherical or ellipsoidal body of the prosthetic implant. The one or more smooth surfaces allow for one or more surfaces of the

generally spherical or ellipsoidal body to become partially or fully fused with one or more vertebrae. The smooth surface can be designed to be adapted to engage and/or anchor the underside surface of a vertebrae within the intervertebral disc space. In one embodiment, at least a portion of the surface of the generally spherical or ellipsoidal body is coated with a material that forms a smooth surface. The coated material can be biologically neutral or can include one or more substances that inhibit and/or promote bone or other tissue growth. In still another aspect of the embodiment, the coated material includes, but is not limited to, a natural and/or synthetic bone cement; polymer, co-polymer and/or urethane foam; autologous growth compound, powdered bone, bone and/or other tissue growth stimulating substances, bone, polyglycolate polymers or analogues, lactides, polydioxamone, polyglycolate, lactide/glycolide copolymers, and/or other tissue growth inhibiting substances and/or medicines. In another embodiment, the coated material can be applied to the generally spherical or ellipsoidal body by adhesive bonding, welding, soldering, shrink wrapping, melting, spray coating, hot dipping, electroplating, immersion coating, brush coating, and/or the like. The coated material can be biologically neutral or include one or more substances that inhibit bone and/or other tissue growth. In one aspect of this embodiment, the coating includes one or more substances that migrate from the coated material into the surrounding tissue. In one specific design, the one or more substances are inserted in, entrapped in and/or at least partially bonded to the coated material so as to at least partially control the time of release and/or release rate of the one or more substances into the surrounding tissue. In another embodiment, the coating material enhances the strength and/or durability of the prosthetic implant and/or hardens or softens the surface of the prosthetic implant.

In accordance with still another aspect of the present invention, the generally spherical or ellipsoidal body of the prosthetic implant includes one or more non-smooth surfaces and/or openings into the generally spherical or ellipsoidal body to promote bone growth and/or other tissue growth into the surface and/or interior of the generally spherical or ellipsoidal body of the prosthetic implant. The one or more non-smooth surfaces and/or openings in the generally spherical or ellipsoidal body allow one or more surfaces of the generally spherical or ellipsoidal body to become partially or fully fused with one or more vertebrae. The non-smooth surface can be designed to be adapted to engage with and/or anchor to the underside surface of a vertebrae

within the intervertebral disc space. In one embodiment, the non-smooth surfaces include, but are not limited to, ridges, grooves, pits, holes, notches, slits, slots, channels, corrugations, and the like. In another embodiment, at least a portion of the surface of the generally spherical or ellipsoidal body is coated with a material that forms a non-smooth surface. The coated material is typically biocompatible. The coated material can be biologically neutral or include one or more substances that inhibit or promote bone and/or other tissue growth. In still another aspect of the embodiment, the coated material includes, but is not limited to, a natural and/or synthetic bone cement, polymer, co-polymer and/or urethane foam, autologous growth compound, powdered bone, bone and/or other tissue growth stimulating substances, bone, polyglycolate polymers or analogues, lactides, polydioxamone, polyglycolate, lactide/glycolide copolymers, and/or other tissue growth inhibiting substances and/or medicines. In another embodiment, the coated material can be applied to the generally spherical or ellipsoidal body by adhesive bonding, welding, soldering, shrink wrapping, melting, spray coating, hot dipping, electroplating, immersion coating, brush coating, and/or the like. The coated material can be biologically neutral or include one or more substances that inhibit bone and/or other tissue growth. In one aspect of this embodiment, the coating includes one or more substances that migrate from the coated material into the surrounding tissue. In one specific design, the one or more substances are inserted in, entrapped in and/or at least partially bonded to the coated material so as to at least partially control the time of release and/or release rate of the one or more substances into the surrounding tissue. In another embodiment, the coating material enhances the strength and/or durability of the prosthetic implant and/or hardens or softens the surface of the prosthetic implant.

In accordance with yet another aspect of the present invention, the generally spherical or ellipsoidal body includes one or more internal cavities. These cavities can include one or more passageways to the outer surface of the generally spherical or ellipsoidal body, or be at least partially isolated from the outer surface of the generally spherical or ellipsoidal body. In one embodiment, at least one of the cavities is substantially vacant. In another embodiment, at least one of the cavities includes one or more substances that promote the effectiveness of the prosthetic implant between at least two vertebrae. In one aspect of this embodiment, at least one of the substances include, but is not limited to, a substance which facilitates in the formation of

a graft between one or more vertebrae. Such substance can include, but is not limited to, medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and the like. In another aspect of this embodiment, at least one of the substances include, but is not limited to, a chemical compound that promotes bone or other tissue growth which inhibits rejection of the prosthetic implant, reduces infection, reduces inflammation, reduces pain, promotes healing of surrounding tissue, functions as a location and/or visual indicator, and/or the like. In still another aspect of this embodiment, one or more cavities are filled with bone material or a synthetic material, with or without a bone activating matter, such as hydroxyapatite bone or proteins, bone growth factor, or cartilage activation factor. In still yet another embodiment, one or more of the cavities in the outer surface of the generally spherical or ellipsoidal body allows blood supply and/or other body fluids to flow into and/or out of one or more of the cavities. In a further embodiment, the size or the passageway and/or opening to the outer surface of the generally spherical or ellipsoidal body can be selected to control the amount and/or rate of the one or more substances in the one or more cavities that exits the cavities. In yet a further embodiment, the size or the passageway and/or opening to the outer surface of the generally spherical or ellipsoidal body can be selected to control the amount and/or rate of bone and/or other tissue growth that occurs in the opening and/or passageway and into the one or more cavities. In still another embodiment, the substance in one or more cavities can be at least partially pre-packed in the cavity prior to inserting the prosthetic implant between one or more vertebrae, and/or the substance can be at least partially packed into one or more cavities after the prosthetic implant is inserted between one or more vertebrae. In still yet another embodiment, the volume of each of the one or more cavities in the generally spherical or ellipsoidal body is less than the total volume of the generally spherical or ellipsoidal body. In one aspect of this embodiment, the volume of each of the one or more cavities in the generally spherical or ellipsoidal body is less than about 50% of the total volume of the generally spherical or ellipsoidal body. The volume of two or more cavities can be the same or different. In another aspect of this embodiment, the volume of each of the one or more cavities in the generally spherical or ellipsoidal body is less than about 40% of the total volume of the generally spherical or ellipsoidal body. In still another aspect of this embodiment, the volume of each of the one or more cavities in the generally spherical or ellipsoidal body is less than about 30% of the total

volume of the generally spherical or ellipsoidal body. In yet another aspect of this embodiment, the volume of each of the one or more cavities in the generally spherical or ellipsoidal body is less than about 20% of the total volume of the generally spherical or ellipsoidal body. In still yet another aspect of this embodiment, the volume of each of the one or more cavities in the generally spherical or ellipsoidal body is less than about 10% of the total volume of the generally spherical or ellipsoidal body. In still yet another embodiment, the sum of the volumes of the one or more cavities in the generally spherical or ellipsoidal body is less than the total volume of the generally spherical or ellipsoidal body. In one aspect of this embodiment, the sum of the volumes of the one or more cavities in the generally spherical or ellipsoidal body is less than about 50% of the total volume of the generally spherical or ellipsoidal body. In another aspect of this embodiment, the sum of the volumes of the one or more cavities in the generally spherical or ellipsoidal body is less than about 40% of the total volume of the generally spherical or ellipsoidal body. In still another aspect of this embodiment, the sum of the volumes of the one or more cavities in the generally spherical or ellipsoidal body is less than about 30% of the total volume of the generally spherical or ellipsoidal body. In yet another aspect of this embodiment, the sum of the volumes of the one or more cavities in the generally spherical or ellipsoidal body is less than about 20% of the total volume of the generally spherical or ellipsoidal body. In still yet another aspect of this embodiment, the sum of the volumes of the one or more cavities in the generally spherical or ellipsoidal body is less than about 10% of the total volume of the generally spherical or ellipsoidal body. In yet another embodiment of the invention, at least two of the cavities in the generally spherical or ellipsoidal body intersect one another. In one aspect of this embodiment, two or more cavities intersect one another at substantially the center of the generally spherical or ellipsoidal body. In another aspect of this embodiment, two or more cavities intersect one another generally off center of the generally spherical or ellipsoidal body. In still yet another embodiment of the invention, at least one of the cavities in the generally spherical or ellipsoidal body at least partially includes a generally cylindrical portion. In one aspect of this embodiment, at least one of the cavities in the generally spherical or ellipsoidal body is substantially cylindrical.

In accordance with still yet another aspect of the present invention, the generally spherical or ellipsoidal body of the prosthetic implant includes one or more openings in the outer wall of

the generally spherical or ellipsoidal body of the prosthetic implant to facilitate in the positioning of the prosthetic implant between the vertebrae and/or to secure the prosthetic implant in place within the intervertebral disc space. In one embodiment, one or more of the openings in the outer wall of the

5 generally spherical or ellipsoidal body is adapted to receive an instrument for guiding and/or inserting the prosthetic implant between the vertebrae of the spine by an anterior, posterior, lateral, and/or latroscopic approach into the spinal column. The one or more openings allow a surgeon to select the best approach for inserting the prosthetic implant in the intervertebral disc space. In one aspect of this embodiment, the instrument opening includes a securing mechanism
10 such as, but not limited to, a thread, in the opening to secure the instrument within the opening.

In accordance with still yet another aspect of the present invention, the generally spherical or ellipsoidal body of the prosthetic implant includes one or more openings in the outer wall of the generally spherical or ellipsoidal body of the prosthetic implant that can be at least partially closed

15 prior to, during and/or after the prosthetic implant is inserted between one or more vertebrae. In one embodiment, a cap is used to at least partially close one or more openings in the generally spherical or ellipsoidal body. In one aspect of this embodiment, the cap substantially seals one or more openings. In another aspect of this embodiment, the cap alters the size of the one or more openings. The altered size of the one or more openings can be used to control the amount
20 and/or rate of substances exiting the one or more openings and/or to control the rate and/or amount of substances, bone and/or other tissue entering the opening. In another aspect of this embodiment, the cap can be made of a porous material or a non-porous material. In another embodiment, the cap is adapted to receive an instrument for guiding and/or inserting the cap into one or more openings in the generally spherical or ellipsoidal body. In still another embodiment,
25 the cap is made of a biocompatible material. In one aspect of this embodiment, the cap is made or includes a material that is the same as the material make-up of the generally spherical or ellipsoidal body. In another aspect of this embodiment, the cap is made of or includes a material that is different from the material of the generally spherical or ellipsoidal body. In yet another embodiment, the cap is made of a material that fuses with the surrounding bone and/or tissue
30 while the prosthetic implant is between one or more vertebrae. In yet another embodiment, the

cap is made of a material that resists fusion with the surrounding bone and/or tissue while the prosthetic implant is between one or more vertebrae. In still yet another embodiment, the cap is made of a material that decomposes after the prosthetic implant is positioned between one or more vertebrae.

5 In accordance with another aspect of the present invention, at least one or more surfaces of the prosthetic implant are rounded off so as not to be sharp. Rounding off the surfaces reduces and/or eliminates pinching of the nerve leading from the spinal cord which can result in pain, damage and/or paralysis to the individual. The rounded surfaces avoid or minimize nerve pressure that can be exerted on the nerves intervertebrally exiting the spinal cord. The one or
10 more rounded off surfaces also facilitate with the insertion of the prosthetic implant within the intervertebral disc space. In one embodiment, substantially all the surfaces of the prosthetic implant are rounded off. In accordance with still another aspect of the present invention, the prosthetic implant includes at least one stabilizer positioned at least partially about the outer surface of the generally spherical or ellipsoidal body of the prosthetic implant. The stabilizer is
15 designed to facilitate in at least partially orienting the prosthetic implant between one or more vertebrae, limiting the amount of movement of the generally spherical or ellipsoidal body between one or more vertebrae and/or facilitating in the insertion of the prosthetic implant between one or more vertebrae. In one embodiment, at least one stabilizer is positioned substantially about the generally spherical or ellipsoidal body. In one aspect of this embodiment,
20 at least one stabilizer is positioned substantially about the central axis of the generally spherical or ellipsoidal body. In another aspect of this embodiment, at least one stabilizer is positioned substantially off-center of the central axis of the generally spherical or ellipsoidal body. In another embodiment, the stabilizer is substantially disc shaped; however, the shape of the stabilizer is in no way limited to such a shape. In yet another embodiment, the stabilizer includes
25 one or more tapered edges. In still another embodiment, the stabilizer is at least partially made of a porous material, a non-porous material, a non-biodegradable material, and/or a biodegradable material. In still yet another embodiment, the stabilizer can be coated with, contain and/or be made of a substance that promotes bone and/or other tissue growth, to inhibit rejection of the prosthetic implant, reduce infection, reduce inflammation, reduce pain, promote
30 healing of surrounding tissue, function as a location and/or visual indicator, and/or the like. In

one aspect of this embodiment, the stabilizer includes, but is not limited to, a substance that includes medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, and/or bone activating matter. In another aspect of this embodiment, the stabilizer includes, but is not limited to, a substance that includes bone, stainless steel, titanium, chromemolybdenum, cobalt chromium alloy, ceramic (zirconium oxide ceramic, aluminum oxide ceramic, etc.), chrome or chrome alloys, cobalt or cobalt alloys, polycarbonate, polypropylene, polyethylene, polymethylmethacrylate, polysulfone types filled with glass and/or carbon fibers, and various types of carbon and fiber reinforced polymers. In one aspect of this embodiment, the material is wear resistant. In another aspect of this embodiment, the material has an increased frictional coefficient. In still another aspect of this embodiment, the material has a reduced frictional coefficient. In still another aspect of this embodiment, the stabilizer and/or coating that is at least partially coated can be made of a material that results in smooth surfaces, rough surfaces, low frictional surfaces, wear resistant surfaces, and/or the like. In another embodiment, the stabilizer can include one or more openings and/or cavities. The openings and/or cavities can include various types of substances to promote bone and/or other tissue growth, inhibit rejection of the prosthetic implant, reduce infection, reduce inflammation, reduce pain, promote healing of surrounding tissue, function as a location and/or visual indicator, and/or the like. In still another embodiment, the stabilizer includes a coating with one or more substances that migrate from the coated material into the surrounding tissue. In one specific design, the one or more substances are inserted in, entrapped in and/or at least partially bonded to the coated material so as to at least partially control the time of release and/or release rate of the one or more substances into the surrounding tissue. In another embodiment, the coating material enhances the strength and/or durability of the prosthetic implant and/or hardens or softens the surface of the stabilizer. In a further embodiment, the stabilizer can be detached from, or is substantially permanently connected to, the generally spherical or ellipsoidal body of the prosthetic implant. In one aspect of this embodiment, the stabilizer and the generally spherical or ellipsoidal body constitute a single component. In still yet a further embodiment, the maximum radial width of the stabilizer is less than about three times the maximum radius of the generally spherical or ellipsoidal body of the prosthetic implant. In one aspect of this embodiment, the maximum radial width of the stabilizer is no more than about two times the maximum radius of the generally spherical or

ellipsoidal body of the prosthetic implant. In another embodiment, the angle of articulation of the stabilizer in relation to the outer surface of the generally spherical or ellipsoidal body can be constant or vary from an angle of less than about 0.01° to about 180° . In still another embodiment, the maximum thickness of the stabilizer is generally less than or equal to the maximum diameter of the generally spherical or ellipsoidal body. In one aspect of this embodiment, the maximum thickness of the stabilizer is less than the maximum diameter of the generally spherical or ellipsoidal body. In another aspect of this embodiment, the maximum thickness of the stabilizer at least closely adjacent to the generally spherical or ellipsoidal body is greater than or equal to the maximum thickness of the stabilizer at the outer edge of the stabilizer. In one particular design, the width of the stabilizer reduces from a point at least closely adjacent to the generally spherical or ellipsoidal body to the outer edge of the stabilizer. In a specific design, the taper is generally constant.

It is an object of the present invention to provide an improved prosthetic implant for insertion between two vertebrae.

It is another and/or alternative object of the present invention to provide a prosthetic implant which at least partially emulates the space between the vertebrae.

Yet another and/or alternative object of the present invention is to provide a prosthetic implant which includes one or more non-smooth surfaces to help secure the prosthetic implant in position between the vertebrae.

It is still yet another and/or alternative object of the present invention to provide a prosthetic implant which provides improved spinal support fixation and methodology which provides stability between adjacent vertebrae and in which the shape will facilitate in securing the prosthetic implant between the vertebrae.

A further and/or alternative object of the present invention is to provide a prosthetic implant that includes a generally spherical or ellipsoidal body.

Still a further and/or alternative object of the present invention is to provide a prosthetic implant that includes a stabilizer.

Yet a further and/or alternative object of the present invention is to provide a prosthetic implant that includes one or more smooth surfaces to inhibit bone and/or other tissue growth on the smooth surface.

Still yet another and/or alternative object of the present invention is to provide a prosthetic implant that includes a cap to at least partially alter the size of an opening in the outer surface of the prosthetic implant.

Another and/or alternative object of the present invention is to provide an apparatus
5 which will at least partially aid in the positioning of the prosthetic implant between the vertebrae.

Still yet another and/or alternative object of the present invention is to provide a prosthetic implant which has one or more openings that can receive packing material to facilitate in the fusion of two adjacently positioned vertebrae and/or the healing process after insertion of the prosthetic implant.

10 A further and/or alternative object of the present invention is to provide a prosthetic implant which can be easily and efficiently positioned between two vertebrae and which reduces the failure rate of prosthetic implants between the vertebrae.

It is still another and/or alternative object of the present invention to provide a prosthetic implant which includes one or more surfaces that reduce pinching with the spinal cord and other
15 body parts closely adjacent to the prosthetic implant.

It is another and/or alternative object of the present invention to provide a prosthetic implant that is at least partially made of a biologically compatible material.

It is another and/or alternative object of the present invention to provide a prosthetic implant that is at least partially made of and/or includes a material that enhances the visibility
20 of the implant when exposed to X-rays, sound waves, light waves, magnetic waves, and/or various other types of electromagnetic waves.

It is another and/or alternative object of the present invention to provide a prosthetic implant that is at least partially made of a material which closely approximates the elasticity of the vertebrae and/or the intervertebral disc.

25 These and other objects of the invention will become apparent to those skilled in the art upon reading and understanding the following detailed description of preferred embodiments taken together with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take physical form in certain parts and arrangement of parts, preferred
30 embodiments of which will be described in detail and illustrated in the accompanying drawings

which form a part hereof and wherein:

FIGURE 1 is an enlarged perspective view of the prosthetic implant of the present invention;

5 FIGURE 2 is an enlarged side elevation view of a portion of a spinal column which includes the prosthetic implant of the present invention positioned between two adjacently positioned vertebrae;

FIGURE 3 is an enlarged perspective view of a modified prosthetic implant of the present invention;

10 FIGURE 4 is an enlarged perspective view of another modified prosthetic implant of the present invention;

FIGURE 5 is an enlarged perspective view of still another modified prosthetic implant of the present invention;

FIGURE 6 is an enlarged perspective view of yet another modified prosthetic implant of the present invention;

15 FIGURE 7 is an enlarged perspective view of still yet another modified prosthetic implant of the present invention;

FIGURE 8 is an enlarged perspective view of a further modified prosthetic implant of the present invention;

20 FIGURE 9 is an enlarged sectional view of the surface of the prosthetic implant illustrating a coating material applied to a smooth outer surface of the body of the prosthetic implant;

FIGURE 10 is an enlarged sectional view of the surface of the prosthetic implant illustrating a coating material applied to an outer surface of the body of the prosthetic implant that has a plurality of openings;

25 FIGURE 11 is an enlarged sectional view of the surface of the prosthetic implant illustrating a coating material applied to a non-smooth outer surface of the body of the prosthetic implant that has a plurality of openings; and,

30 FIGURE 12 is an enlarged sectional view of the surface of the prosthetic implant illustrating a coating material having a non-smooth surface applied to the outer surface of the body of the prosthetic implant.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, wherein the showings are for the purpose of illustrating the preferred embodiment of the invention only and not for the purpose of limiting same, FIGURES 1, and 3-8 illustrate a prosthetic device or implant 10 which is designed to be inserted in an intervertebral disc space between two vertebrae of the spinal column. Prosthetic implant 10 is illustrated as having a spherical body 20 that has an outer surface 22. spherical body 20 can be made of a variety of materials such as, but not limited to, bone, stainless steel, titanium, chromemolybdenum, cobalt chromium alloy, ceramic (zirconium oxide ceramic, aluminum oxide ceramic, etc.), chrome or chrome alloys, cobalt or cobalt alloys, polycarbonate, polypropylene, polyethylene, polymethylmethacrylate, polysulfone types filled with glass and/or carbon fibers, and various types of carbon and fiber reinforced polymers. The particular material or materials selected will generally depend on the location of the implant and the various objectives to be accomplished by the implant. Additionally, spherical body 20 can include medicine, bone and/or tissue growth promoters, bone and/or tissue growth inhibitors, etc. that are mixed with the materials of spherical body 20 which are designed to flow or otherwise escape from spherical body 20 and enter the bone, tissue and/or fluids about the implant, and/or interact with the bone, tissue and/or fluids about the implant.

Referring now to FIGURE 1, implant 10 includes a spherical body 20 that has an outer surface 22 which is substantially smooth. The interior of spherical body 20 can be solid, hollow or have one or more cavities. If spherical body 20 includes one or more cavities, the cavities can be empty or at least partially filled with a material which alters the physical characteristics of spherical body 20 (i.e. weight distribution, density distribution, etc.) and/or which is designed to flow or otherwise escape the void and enter the bone, tissue and/or fluids about the implant (i.e. medicine, bone and/or tissue growth promoters, bone and/or tissue growth inhibitors, etc.). Implant 10 also includes a stabilizer 30 connected to spherical body 20. Stabilizer 30 is disc shaped and extends about the central axis of spherical body 20. Stabilizer 30 and spherical body 20 are shown to be formed of a single piece of material. Generally, the stabilizer is made of a similar material as spherical body 20; however, the stabilizer can include different or additional materials. As can be appreciated, stabilizer 30 can be a separate component that is later connected to outer surface 22. Stabilizer 30 is designed to facilitate in at least partially orienting

the prosthetic implant between one or more vertebrae, limiting the amount of movement of the generally spherical or ellipsoidal body between one or more vertebrae, and/or facilitating in the insertion of the prosthetic implant between one or more vertebrae. Edge 32 of stabilizer 30 is a rounded, non-sharp edge. The rounding off of the surfaces of the stabilizer reduces and/or eliminates pinching of the nerve leading from the spinal cord which can result in pain, damage and/or paralysis to the individual. Stabilizer 30 also has a thickness that reduces as the distance increases from spherical body 20. Stabilizer 30 also has a maximum thickness that is less than the diameter of spherical body 20. Generally, the maximum thickness of the stabilizer is less than about 1.5 times the diameter of spherical body 20, and typically less than about 4 times the diameter of spherical body 20. Stabilizer 30 is shown to have a generally constant width that radially extends outwardly from spherical body 20; however, the width of the stabilizer can vary. Generally, the maximum width of the stabilizer is less than about 2 times the diameter of spherical body 20, and typically less than about 1 times the diameter of spherical body 20.

Referring now to FIGURE 2, implant 10 is shown as being inserted into a human vertebrae column 40. Human vertebrae column 40 includes several vertebrae 42, 44, 46 and includes intervertebral disc 50 positioned between two adjacently positioned vertebrae. Implant 10 is designed to partially or fully replace a damaged intervertebral disc. As shown in FIGURE 2, vertebrae 42 and 44 are separated by, and at least partially supported on, spherical body 20 of prosthetic implant 10. The remaining vertebrae are illustrated as being supported on, and separated by, intervertebral disc 50 which maintains a space between the adjoining vertebrae. The damaged portions of intervertebral disc 50 have been removed from the region between vertebrae 42 and 44 prior to prosthetic implant 10 being inserted therebetween. The inner surfaces of vertebrae 42 and 44 are also prepared prior to implant 10 being inserted therebetween. Such preparation typically includes cleaning the region between the vertebrae of unwanted materials, removing bone and/or tissue from the surface of one or more vertebrae, inserting separators between the vertebrae, and the like. After the region between the vertebrae has been prepared, implant 10 is inserted into the space between the vertebrae. Depending of the design of implant 10, the prosthetic implant will achieve arthrodesis (fusion) and/or arthroplasty (joint formation) between adjacent vertebrae. Once implant 10 has been inserted between vertebrae 42 and 44, stabilizer 30 limits the movement of implant 10 between the vertebrae.

Referring now to FIGURES 3-8, other designs of the prosthetic implant are illustrated. Referring specifically to FIGURE 3, prosthetic implant 10 includes a spherical body 20 that has a substantially smooth outer surface 22. The interior of spherical body 20 can be solid, hollow or have one or more cavities. If spherical body 20 includes one or more cavities, the cavities can be empty or at least partially filled with a material which alters the physical characteristics of spherical body 20 (i.e. weight distribution, density distribution, etc.) and/or which is designed to flow or otherwise escape the void and enter the bone, tissue and/or fluids about the implant (i.e. medicine, bone and/or tissue growth promoters, bone and/or tissue growth inhibitors, etc.). Implant 10 is also shown has not having a stabilizer. Spherical body 20 includes several openings 60, 64 and 70. The openings are illustrated as being circular shaped; however, other shapes can be used. The size of the openings is selected so that various materials can be pack therein and/or to enable bone and/or tissue to grow in the opening to facilitate in the fusion of the body to a vertebrae. When materials are packed into the openings, the packed material typically includes, but is not limited to, medicine, tissue, cells, and the like. One or more of the openings can also be used to enable an instrument to be connected to the implant to facilitate in the insertion and/or positioning of the implant between the vertebrae. The instrument can be used to insert the prosthetic implant in the intervertebral disc space in a number of different approaches such as from an anterior, posterior, lateral, and/or lateralscopic approach to the vertebrae. The opening for the instrument is typically threaded to receive a threaded instrument. The threaded opening allows an instrument to be simply secured to and/or removed from the prosthetic implant 10. The instrument opening can also be used to secure pedicle screws to the prosthetic implant to facilitate in the attachment of a rod or plate stabilization system to the prosthetic implant.

Referring now to FIGURE 4, prosthetic implant 10 includes a spherical body 20 that has a substantially smooth outer surface 22. Implant 10 is also shown has not having a stabilizer. Implant 10 also includes a plurality of cavities 80, 82 and 84. The cavities have a substantially cylindrical shape and extend through implant 10. The cavities are illustrated as all passing through the center of spherical body 20; however, it can be appreciated that one or more of the cavities do not pass through the center of spherical body 20. Cavity 80 includes openings 60 and 62, cavity 82 includes openings 68 and 70 and cavity 84 includes openings 64 and 66. The

cavities typically include material packed therein; however, the cavities can be empty to allow fluids to flow therethrough. One or more of the openings can also be used to enable an instrument to be connected to the implant to facilitate in the insertion and/or positioning of the implant between the vertebrae. The remaining portion of the interior of spherical body 20 can be solid, hollow or have one or more cavities. If spherical body 20 includes one or more of these cavities, the cavities can be empty or at least partially filled with a material which alters the physical characteristics of spherical body 20 (i.e. weight distribution, density distribution, etc.) and/or which is designed to flow or otherwise escape the void and enter the bone, tissue and/or fluids about the implant (i.e. medicine, bone and/or tissue growth promoters, bone and/or tissue growth inhibitors, etc.).

Referring now to FIGURE 5, prosthetic implant 10 includes a spherical body 20 that has a substantially smooth outer surface 22. Implant 10 is also shown has not having a stabilizer. Implant 10 is further illustrated as not having any openings. The interior of spherical body 20 can be solid, hollow or have one or more cavities. If spherical body 20 includes one or more cavities, the cavities can be empty or at least partially filled with a material which alters the physical characteristics of spherical body 20 (i.e. weight distribution, density distribution, etc.) and/or which is designed to flow or otherwise escape the void and enter the bone, tissue and/or fluids about the implant (i.e. medicine, bone and/or tissue growth promoters, bone and/or tissue growth inhibitors, etc.).

Referring now to FIGURE 6, prosthetic implant 10 includes a spherical body 20 that has a substantially smooth outer surface 22. Implant 10 is also shown has not having a stabilizer. Implant 10 is further illustrated as having two openings 60 and 62 and a cylindrical cavity 80 extending therebetween. The cavities typically include material packed therein; however, the cavities can be empty to allow fluids to flow therethrough. The single cavity is illustrated as having a volume that is greater than the individual volumes of cavities 80, 82 and 84 of FIGURE 4. Typically the volume of cavity 80 of FIGURE 6 is less than half the volume of spherical body 20. The remaining portion of the interior of spherical body 20 can be solid, hollow or have one or more cavities. If spherical body 20 includes one or more of these cavities, the cavities can be empty or at least partially filled with a material which alters the physical characteristics of spherical body 20 (i.e. weight distribution, density distribution, etc.) and/or which is designed

to flow or otherwise escape the void and enter the bone, tissue and/or fluids about the implant (i.e. medicine, bone and/or tissue growth promoters, bone and/or tissue growth inhibitors, etc.).

Referring now to FIGURE 7, implant 10 is similar to the implant shown in FIGURE 3, but includes a single opening 60. Opening 60 includes a threaded interior 72 that is designed to receive an instrument as described above and/or a cap 120. Cap 120 includes threading 122 that threads into opening 60 to at least partially close opening 60.

Referring now to FIGURE 8, implant 10 is similar to the implant shown in FIGURE 7, but outer surface 22 is a non-smooth surface. The non-smooth surface openings enable the implant to become partially or fully fused with one or more vertebrae. The non-smooth surface can also be designed to engage with and/or anchor to the underside surface of a vertebrae within the intervertebral disc space.

Referring now to FIGURES 9-12, an implant is shown to have an outer surface 22 that is at least partially coated with a coating 90. Coating 90 can form a substantially smooth outer surface 92 as shown in FIGURES 9-11 or have a non-smooth surface 92 as shown in FIGURE 12. Coating 90 can be made of a variety of materials. Typically, coating 90 includes one or more materials that is different from the material composition of the outer surface 22 of spherical body 20. Coating 90 can also have a variety of functions such as, but not limited to, forming a substantially smooth and durable surface over a substantially smooth outer surface 22 of spherical body 20 as shown in FIGURE 9, forming a substantially smooth and durable surface over a substantially smooth outer surface 22 of spherical body 20 and to at least partially cover openings 100 in the surface of spherical body 20 as shown in FIGURE 10, forming a substantially smooth and durable surface of the prosthetic implant over a non-smooth outer surface 22 of spherical body 20 and to at least partially cover openings 100 in the surface of spherical body 20 as shown in FIGURE 11, or forming a non-smooth surface over a substantially smooth outer surface 22 of spherical body 20 as shown in FIGURE 12. As can be appreciated, coating 90 can be at least partially coated onto the stabilizer of the implant when the implant includes a stabilizer.

As shown in FIGURE 10, a substance 110 flows from opening 100 and through coating 90. Coating 90 can be formulated to control the flow rate of substance 110 out of opening 100. The substance can be any number of materials that promote bone and/or other tissue growth,

inhibit rejection of the prosthetic implant, reduce infection, reduce inflammation, reduce pain, promote healing of surrounding tissue, function as a location and/or visual indicator, and/or the like. Referring now to FIGURES 11 and 12, coating 90 includes a substance 112 that is released from the coating. This substance can be any number of materials that promote bone and/or other
5 tissue growth, inhibit rejection of the prosthetic implant, reduce infection, reduce inflammation, reduce pain, promote healing of surrounding tissue, function as a location and/or visual indicator, and/or the like.

The invention has been described with reference to the preferred embodiments. These and other modifications of the preferred embodiments as well as other embodiments of the
10 invention will be obvious from the disclosure herein, whereby the foregoing descriptive matter is to be interpreted merely as illustrative of the invention and not as a limitation. It is intended to include all such modifications and alterations insofar as they come within the scope of the appended claims.

We claim:

1. A prosthetic implant to at least partially support adjoining vertebrae in a spinal column, comprising a prosthetic implant having a substantially spherical or ellipsoidal body that includes at least one non-growth outer surface that at least partially inhibits growth on said outer surface while positioned between adjoining vertebrae.
2. The prosthetic implant as defined in claim 1, wherein said at least one non-growth outer surface having a surface area, said surface area being at least about 80 percent of a total outer surface area of said substantially spherical or ellipsoidal body.
3. The prosthetic implant as defined in claim 1, wherein said body including at least one opening.
4. The prosthetic implant as defined in claim 1, wherein at least a portion of said non-growth outer surface is formed by a coating material applied to said outer surface of said substantially spherical or ellipsoidal body.
5. The prosthetic implant as defined in claim 3, wherein at least a portion of said non-growth outer surface is formed by a coating material applied to said outer surface of said substantially spherical or ellipsoidal body.
6. The prosthetic implant as defined in claim 5, wherein said coating material at least partially covering at least one opening in said outer surface of said substantially spherical or ellipsoidal body.
7. The prosthetic implant as defined in claim 3, wherein at least one opening including a substance to at least partially inhibit tissue growth in said opening.
8. The prosthetic implant as defined in claim 6, wherein at least one opening including a substance to at least partially inhibit tissue growth in said opening.

9. The prosthetic implant as defined in claim 4, wherein said coating material including a substance to at least partially inhibit tissue growth on said coating material.
10. The prosthetic implant as defined in claim 8, wherein said coating material including a substance to at least partially inhibit tissue growth on said coating material.
11. The prosthetic implant as defined in claim 1, wherein said non-growth outer surface includes a substantially smooth surface.
12. The prosthetic implant as defined in claim 5, wherein said non-growth outer surface includes a substantially smooth surface.
13. The prosthetic implant as defined in claim 1, wherein said non-growth outer surface includes a substantially non-smooth surface.
14. The prosthetic implant as defined in claim 5, wherein said non-growth outer surface includes a substantially non-smooth surface.
15. The prosthetic implant as defined in claim 1, including at least one stabilizer positioned at least partially about said outer surface of said substantially spherical or ellipsoidal body that at least partially limits movement of said body between said adjoining vertebrae.
16. The prosthetic implant as defined in claim 3, including at least one stabilizer positioned at least partially about said outer surface of said substantially spherical or ellipsoidal body that at least partially limits movement of said body between said adjoining vertebrae.
17. The prosthetic implant as defined in claim 10, including at least one stabilizer positioned at least partially about said outer surface of said substantially spherical or ellipsoidal body that at least partially limits movement of said body between said adjoining vertebrae.

18. The prosthetic implant as defined in claim 11, wherein said stabilizer is substantially disc shaped.

19. The prosthetic implant as defined in claim 11, wherein said stabilizer includes a substance to at least partially inhibit tissue growth on said stabilizer.

20. The prosthetic implant as defined in claim 17, wherein said stabilizer includes a substance to at least partially inhibit tissue growth on said stabilizer.

21. The prosthetic implant as defined in claim 11, wherein said stabilizer includes a substance to at least partially promote tissue growth on said stabilizer.

22. The prosthetic implant as defined in claim 17, wherein said stabilizer includes a substance to at least partially inhibit tissue growth on said stabilizer.

23. The prosthetic implant as defined in claim 1, including an instrument cavity adapted to receive an instrument to guide said prosthetic implant between adjoining vertebrae in a spinal column, to receive an implant to secure said prosthetic implant in position relative to said vertebrae, and combinations thereof.

24. The prosthetic implant as defined in claim 20, including an instrument cavity to adapted to receive an instrument to guide said prosthetic implant between adjoining vertebrae in a spinal column, to receive an implant to secure said prosthetic implant in position relative to said vertebrae, and combinations thereof.

25. The prosthetic implant as defined in claim 23, including a cap to at least partially cover said instrument cavity.

26. The prosthetic implant as defined in claim 24, including a cap to at least partially cover said instrument cavity.

27. A prosthetic implant to at least partially support adjoining vertebrae in a spinal column, comprising a prosthetic implant having a substantially spherical or ellipsoidal body that includes at least one growth promoting outer area, said growth promoting outer area at least partially promoting tissue growth on said growth promoting outer surface while positioned between adjoining vertebrae, said one growth promoting outer area including a substantially smooth surface, a non-smooth surface, an opening, and combinations thereof.

28. The prosthetic implant as defined in claim 27, wherein said at least one growth promoting outer area includes a substance that promotes tissue growth.

29. The prosthetic implant as defined in claim 27, wherein said at least one growth promoting outer area includes at least one opening that at least partially provides fluid access to at least one cavity in the interior of said substantially spherical or ellipsoidal body.

30. The prosthetic implant as defined in claim 28, wherein said at least one growth promoting outer area includes at least one opening that at least partially provides fluid access to at least one cavity in the interior of said substantially spherical or ellipsoidal body.

31. The prosthetic implant as defined in claim 29, wherein at least one of said cavities having a substantially cylindrical shape.

32. The prosthetic implant as defined in claim 30, wherein at least one of said cavities has a substantially cylindrical shape.

33. The prosthetic implant as defined in claim 27, including an instrument cavity adapted to receive an instrument to guide said prosthetic implant between adjoining vertebrae in a spinal column, to receive an implant to secure said prosthetic implant in position relative to said vertebrae, and combinations thereof.

34. The prosthetic implant as defined in claim 32, including an instrument cavity

adapted to receive an instrument to guide said prosthetic implant between adjoining vertebrae in a spinal column, to receive an implant to secure said prosthetic implant in position relative to said vertebrae, and combinations thereof.

35. The prosthetic implant as defined in claim 33, including a cap to at least partially cover said instrument cavity.

36. The prosthetic implant as defined in claim 34, including a cap to at least partially cover said instrument cavity.

37. The prosthetic implant as defined in claim 27, wherein at least a portion of said growth promoting outer area is formed by a coating material applied to an outer surface of said substantially spherical or ellipsoidal body.

38. The prosthetic implant as defined in claim 32, wherein at least a portion of said growth promoting outer area is formed by a coating material applied to an outer surface of said substantially spherical or ellipsoidal body.

39. The prosthetic implant as defined in claim 37, wherein said coating material at least partially covering at least one opening in said outer surface of said substantially spherical or ellipsoidal body.

40. The prosthetic implant as defined in claim 38, wherein said coating material at least partially covering at least one opening in said outer surface of said substantially spherical or ellipsoidal body.

41. The prosthetic implant as defined in claim 37, wherein said coating material including a substance to at least partially promote tissue growth on said coating material.

42. The prosthetic implant as defined in claim 38, wherein said coating material

including a substance to at least partially promote tissue growth on said coating material.

43. The prosthetic implant as defined in claim 27, wherein said growth promoting outer area including a substantially non-smooth surface.

44. The prosthetic implant as defined in claim 42, wherein said growth promoting outer area including a substantially non-smooth surface.

45. The prosthetic implant as defined in claim 27, including at least one stabilizer positioned at least partially about an outer surface of said substantially spherical or ellipsoidal body that at least partially limits movement of said body between said adjoining vertebrae.

46. The prosthetic implant as defined in claim 32, including at least one stabilizer positioned at least partially about an outer surface of said substantially spherical or ellipsoidal body that at least partially limits movement of said body between said adjoining vertebrae.

47. The prosthetic implant as defined in claim 44, including at least one stabilizer positioned at least partially about an outer surface of said substantially spherical or ellipsoidal body that at least partially limits movement of said body between said adjoining vertebrae.

48. The prosthetic implant as defined in claim 45, wherein said stabilizer is substantially disc shaped.

49. The prosthetic implant as defined in claim 45, wherein said stabilizer includes a substance to at least partially promote tissue growth on said stabilizer.

50. The prosthetic implant as defined in claim 47, wherein said stabilizer includes a substance to at least partially promote tissue growth on said stabilizer.

51. A method for promoting arthrodesis or arthroplasty between adjacent spinal

vertebrae comprising:

a. partially or completely removing a ruptured, flattened or degenerated disc located between a pair of adjacent vertebrae having opposed facing surfaces;

5 b. separating the pair of vertebrae;

c. preparing the opposed facing surfaces on the pair of vertebrae for a prosthetic implant; and,

d. inserting the prosthetic implant between said pair of vertebrae, said prosthetic implant having a substantially spherical or ellipsoidal body that includes at least one non-growth outer surface that at least partially inhibits growth on said outer surface while positioned between adjoining vertebrae.

52. A method for promoting arthrodesis or arthroplasty between adjacent spinal vertebrae comprising:

a. partially or completely removing a ruptured, flattened or degenerated disc located between a pair of adjacent vertebrae having opposed facing surfaces;

5 b. separating the pair of vertebrae;

c. preparing the opposed facing surfaces on the pair of vertebrae for a prosthetic implant; and,

10 d. inserting the prosthetic implant between said pair of vertebrae, having a substantially spherical or ellipsoidal body that includes at least one growth promoting outer area, said growth promoting outer area at least partially promoting tissue growth on said growth promoting outer surface while positioned between adjoining vertebrae, said one growth promoting outer area including a substantially smooth surface, a non-smooth surface, an opening, and combinations thereof.

AMENDED CLAIMS

[received by the International Bureau on 29 October 2002 (29.10.02);
claims 1-25 replaced with new claims 1-88]

We claim:

1. A prosthetic implant comprising a prosthetic implant having a substantially spherical or ellipsoidal body being formed of a material designed to maintain a tension load of at least about ten pounds without substantially deforming, less than about 50% of the volume of said substantially spherical or ellipsoidal body constituting one or more cavities.
2. The prosthetic implant as defined in claim 1, wherein said substantially spherical or ellipsoidal body includes an exterior surface, said exterior surface including at least one surface that includes a non-growth outer surface that at least partially inhibits growth on said at least one non-growth outer surface while positioned in a surgical site, a growth promoting outer surface that at least partially promotes tissue growth on said at least one growth promoting outer surface while positioned in a surgical site, and combinations thereof.
3. The prosthetic implant as defined in claim 2, wherein said at least one non-growth outer surface, said at least one growth promoting outer surface, and combinations thereof having a surface area that is a majority of a total outer surface area of said substantially spherical or ellipsoidal body.
4. The prosthetic implant as defined in claim 3, wherein said at least one non-growth outer surface and said growth promoting outer surface having a surface area that is at least about 60% of the total outer surface area of said substantially spherical or ellipsoidal body.
5. The prosthetic implant as defined in claim 4, wherein said at least one non-growth outer surface and said growth promoting outer surface having a surface area that is at least about 80% of the total outer surface area of said substantially spherical or ellipsoidal body.
6. The prosthetic implant as defined in claims 1-5, wherein less than about 30% of said body includes one or more cavities.

7. The prosthetic implant as defined in claims 1-6, wherein at least one of said cavities having a substantially cylindrical shape.

8. The prosthetic implant as defined in claims 1-7, wherein said body including at least one opening that at least partially provides fluid access to at least one cavity in an interior of said substantially spherical or ellipsoidal body.

9. The prosthetic implant as defined in claims 1-8, wherein said at least one cavity at least partially including a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, bone or other tissue growth promoter, implant rejection inhibitor, infection inhibitor, inflammation inhibitor, pain inhibitor, promoter to heal of surrounding tissue, position locator, visual indicator, and combinations thereof.

10. The prosthetic implant as defined in claim 6, wherein said substantially spherical or ellipsoidal body includes substantially no cavities.

11. The prosthetic implant as defined in claims 2-9, wherein at least a portion of said at least one non-growth outer surface is formed by a coating material applied to at least a portion of said exterior surface of said substantially spherical or ellipsoidal body.

12. The prosthetic implant as defined in claims 2-10, wherein at least a portion of said at least one growth promoting outer surface is formed by a coating material applied to at least a portion of said exterior surface of said substantially spherical or ellipsoidal body.

13. The prosthetic implant as defined in claim 9 or 10, wherein said coating material at least partially covering at least one opening in said exterior surface of said substantially spherical or ellipsoidal body.

14. The prosthetic implant as defined in claims 10-13, wherein at least one opening including a substance to at least partially inhibit tissue growth in said opening.

15. The prosthetic implant as defined in claims 10-14, wherein at least one opening including a substance to at least partially inhibit tissue growth in said opening.

16. The prosthetic implant as defined in claims 11-15, wherein said coating material including a substance to at least partially inhibit tissue growth on said coating material.

17. The prosthetic implant as defined in claims 11-16, wherein said coating material including a substance to at least partially promotes tissue growth on said coating material.

18. The prosthetic implant as defined in claims 2-16, wherein said surface that includes said at least one non-growth outer surface, said at least one growth promoting outer surface, and combinations thereof is a substantially smooth surface.

19. The prosthetic implant as defined in claims 2-17, wherein said surface that includes said at least one non-growth outer surface, said at least one growth promoting outer surface, and combinations thereof is a substantially non-smooth surface.

20. The prosthetic implant as defined in claims 1-19, including at least one stabilizer at least partially connected to and positioned at least partially about said exterior surface of said substantially spherical or ellipsoidal body, said at least one stabilizer at least partially limiting movement of said substantially spherical or ellipsoidal body in a surgical site.

21. The prosthetic implant as defined in claim 20, wherein said at least one stabilizer is positioned completely about said exterior surface of said substantially spherical or ellipsoidal body.

22. The prosthetic implant as defined in claim 20 or 21, wherein said at least one stabilizer is positioned substantially about the central axis of said substantially spherical or ellipsoidal body.

23. The prosthetic implant as defined in claims 20-22, wherein said at least one

stabilizer is substantially disc shaped.

24. The prosthetic implant as defined in claims 20-23, wherein said at least one stabilizer includes a substance to at least partially inhibit tissue growth on said at least one stabilizer.

25. The prosthetic implant as defined in claims 20-24, wherein said at least one stabilizer includes a substance to at least partially promote tissue growth on said at least one stabilizer.

26. The prosthetic implant as defined in claims 20-25, wherein said at least one stabilizer includes a coating that includes a substance to at least partially inhibit tissue growth on said at least one stabilizer.

27. The prosthetic implant as defined in claims 20-26, wherein said at least one stabilizer includes a coating that includes a substance to at least partially promote tissue growth on said at least one stabilizer.

28. The prosthetic implant as defined in claims 20-27, wherein said at least one stabilizer includes at least one tapered edge.

29. The prosthetic implant as defined in claims 20-28, wherein said at least one stabilizer includes a substance selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, bone activating matter, and combinations thereof.

30. The prosthetic implant as defined in claims 20-29, wherein said at least one stabilizer includes a substantially smooth surface.

31. The prosthetic implant as defined in claims 20-30, wherein said at least one stabilizer includes a substantially non-smooth surface.

32. The prosthetic implant as defined in claims 20-31, wherein said at least one stabilizer does not include an opening.

33. The prosthetic implant as defined in claim 20-32, wherein said at least one stabilizer has a maximum radial width, said maximum radial width being less than about three times a maximum radius of said substantially spherical or ellipsoidal body.

34. The prosthetic implant as defined in claim 33, wherein said at least one stabilizer has a maximum radial width, said maximum radial width being less than about one times a maximum radius of said substantially spherical or ellipsoidal body.

35. The prosthetic implant as defined in claims 20-34, wherein said at least one stabilizer has a maximum thickness, said maximum thickness being less than a maximum diameter of said substantially spherical or ellipsoidal body.

36. The prosthetic implant as defined in claim 35, wherein said at least one stabilizer has a maximum thickness, said maximum thickness being less than about 1.5 times the maximum diameter of said substantially spherical or ellipsoidal body.

37. The prosthetic implant as defined in claims 20-36, wherein said at least one stabilizer has thickness at least closely adjacent to said substantially spherical or ellipsoidal body that is greater than the maximum thickness of an outer edge of said at least one stabilizer.

38. The prosthetic implant as defined in claim 37, wherein said thickness of said at least one stabilizer reduces at a generally constant rate from at least closely adjacent to said substantially spherical or ellipsoidal body to said outer edge of said at least one stabilizer.

39. The prosthetic implant as defined in claims 20-38, wherein said at least one stabilizer and said substantially spherical or ellipsoidal body are formed from substantially the same material.

40. The prosthetic implant as defined in claims 1-39, wherein said body is substantially spherical.

41. The prosthetic implant as defined in claims 1-40, including an instrument cavity adapted to receive an instrument to guide said prosthetic implant in a surgical site, to receive a connector to secure said prosthetic implant in position, and combinations thereof.

42. The prosthetic implant as defined in claim 41, including a cap to at least partially cover said instrument cavity.

43. The prosthetic implant as defined in claims 1-42, wherein said substantially spherical or ellipsoidal body adapted to at least partially support adjoining vertebrae in a spinal column.

44. The prosthetic implant as defined in claims 1-42, wherein said body includes a substance selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, bone activating matter, and combinations thereof.

45. A method for promoting arthrodesis or arthroplasty between two bones or bone sections comprising:

- a. at least partially preparing the two bones or bone sections for a prosthetic implant; and,
- b. at least partially positioning said prosthetic implant between said two bones or bone sections, said prosthetic implant having a body formed of a material designed to maintain a tension load of at least about ten pounds without substantially deforming, less than about 50% of the volume of said body constituting one or more cavities, said body at least partially including a substantially spherical or ellipsoidal shape.

46. The method as defined in claim 45, wherein said step of at least partially preparing the two bones or bone sections for a prosthetic implant includes partially or

completely removing a ruptured, flattened or degenerated disc located between a pair of adjacent vertebrae having opposed facing surfaces, preparing the opposed facing surfaces on the pair of vertebrae for a prosthetic implant, and at least partially separating the pair of vertebrae.

47. The method as defined in claim 45 or 46, wherein said substantially spherical or ellipsoidal body includes an exterior surface, said exterior surface including at least one surface that includes a non-growth outer surface that at least partially inhibits growth on said at least one non-growth outer surface while positioned in a surgical site, a growth promoting outer surface that at least partially promotes tissue growth on said at least one growth promoting outer surface while positioned in a surgical site, and combinations thereof.

48. The method as defined in claims 45-47, wherein said at least one non-growth outer surface, said at least one growth promoting outer surface, and combinations thereof having a surface area that is a majority of a total outer surface area of said substantially spherical or ellipsoidal body.

49. The method as defined in claim 47, wherein said at least one non-growth outer surface and said growth promoting outer surface having a surface area that is at least about 60% of the total outer surface area of said substantially spherical or ellipsoidal body.

50. The method as defined in claim 48, wherein said at least one non-growth outer surface and said growth promoting outer surface having a surface area that is at least about 80% of the total outer surface area of said substantially spherical or ellipsoidal body.

51. The method as defined in claims 45-49, wherein less than about 30% of said body includes one or more cavities.

52. The method as defined in claims 45-50, wherein at least one of said cavities having a substantially cylindrical shape.

53. The method as defined in claims 45-51, wherein said body including at least one opening that at least partially provides fluid access to at least one cavity in an interior of said substantially spherical or ellipsoidal body.

54. The method as defined in claims 45-52, wherein said at least one cavity at least partially including a material selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, bone or other tissue growth promoter, implant rejection inhibitor, infection inhibitor, inflammation inhibitor, pain inhibitor, promoter to heal of surrounding tissue, position locator, visual indicator, and combinations thereof.

55. The method as defined in claim 50, wherein said substantially spherical or ellipsoidal body includes substantially no cavities.

56. The method as defined in claims 46-54, wherein at least a portion of said at least one non-growth outer surface is formed by a coating material applied to at least a portion of said exterior surface of said substantially spherical or ellipsoidal body.

57. The method as defined in claims 46-55, wherein at least a portion of said at least one growth promoting outer surface is formed by a coating material applied to at least a portion of said exterior surface of said substantially spherical or ellipsoidal body.

58. The method as defined in claim 54 or 55, wherein said coating material at least partially covering at least one opening in said exterior surface of said substantially spherical or ellipsoidal body.

59. The method as defined in claims 53-56, wherein at least one opening including a substance to at least partially inhibit tissue growth in said opening.

60. The method as defined in claims 53-57, wherein at least one opening including a substance to at least partially inhibit tissue growth in said opening.

61. The method as defined in claims 54-58, wherein said coating material including a substance to at least partially inhibit tissue growth on said coating material.

62. The method as defined in claims 54-59, wherein said coating material including a substance to at least partially promotes tissue growth on said coating material.

63. The method as defined in claims 46-61, wherein said surface that includes said at least one non-growth outer surface, said at least one growth promoting outer surface, and combinations thereof is a substantially smooth surface.

64. The method as defined in claims 46-62, wherein said surface that includes said at least one non-growth outer surface, said at least one growth promoting outer surface, and combinations thereof is a substantially non-smooth surface.

65. The method as defined in claims 45-64, including at least one stabilizer at least partially connected to and positioned at least partially about said exterior surface of said substantially spherical or ellipsoidal body, said at least one stabilizer at least partially limiting movement of said substantially spherical or ellipsoidal body in a surgical site.

66. The method as defined in claim 63, wherein said at least one stabilizer is positioned completely about said exterior surface of said substantially spherical or ellipsoidal body.

67. The method as defined in claim 63 or 64, wherein said at least one stabilizer is positioned substantially about the central axis of said substantially spherical or ellipsoidal body.

68. The method as defined in claims 63-65, wherein said at least one stabilizer is substantially disc shaped.

69. The method as defined in claims 63-66, wherein said at least one stabilizer includes a substance to at least partially inhibit tissue growth on said at least one stabilizer.

70. The method as defined in claims 63-67, wherein said at least one stabilizer includes a substance to at least partially promote tissue growth on said at least one stabilizer.

71. The method as defined in claims 63-68, wherein said at least one stabilizer includes a coating that includes a substance to at least partially inhibit tissue growth on said at least one stabilizer.

72. The method as defined in claims 63-69, wherein said at least one stabilizer includes a coating that includes a substance to at least partially promote tissue growth on said at least one stabilizer.

73. The method as defined in claims 63-70, wherein said at least one stabilizer includes at least one tapered edge.

74. The method as defined in claims 63-71, wherein said at least one stabilizer includes a substance selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, bone activating matter, and combinations thereof.

75. The method as defined in claims 63-72, wherein said at least one stabilizer includes a substantially smooth surface.

76. The method as defined in claims 63-73, wherein said at least one stabilizer includes a substantially non-smooth surface.

77. The method as defined in claims 63-74, wherein said at least one stabilizer does not include an opening.

78. The method as defined in claim 63-75, wherein said at least one stabilizer has a maximum radial width, said maximum radial width being less than about three times a maximum radius of said substantially spherical or ellipsoidal body.

79. The method as defined in claim 76, wherein said at least one stabilizer has a maximum radial width, said maximum radial width being less than about one times a maximum radius of said substantially spherical or ellipsoidal body.

80. The method as defined in claims 63-77, wherein said at least one stabilizer has a maximum thickness, said maximum thickness being less than a maximum diameter of said substantially spherical or ellipsoidal body.

81. The method as defined in claim 78, wherein said at least one stabilizer has a maximum thickness, said maximum thickness being less than about 1.5 times the maximum diameter of said substantially spherical or ellipsoidal body.

82. The method as defined in claims 63-79, wherein said at least one stabilizer has thickness at least closely adjacent to said substantially spherical or ellipsoidal body that is greater than the maximum thickness of an outer edge of said at least one stabilizer.

83. The method as defined in claim 80, wherein said thickness of said at least one stabilizer reduces at a generally constant rate from at least closely adjacent to said substantially spherical or ellipsoidal body to said outer edge of said at least one stabilizer.

84. The method as defined in claims 63-81, wherein said at least one stabilizer and said substantially spherical or ellipsoidal body are formed from substantially the same material.

85. The method as defined in claims 45-82, wherein said body is substantially spherical.

86. The method as defined in claims 45-83, including an instrument cavity adapted to receive an instrument to guide said prosthetic implant in a surgical site, to receive a connector to secure said prosthetic implant in position in a surgical site, and combinations thereof.

87. The method as defined in claim 84, including a cap to at least partially cover said instrument cavity.

88. The method as defined in claims 45-87, wherein said body includes a substance selected from the group consisting of medicine, human tissue, animal tissue, synthetic tissue, human cells, animal cells, synthetic cells, bone activating matter, and combinations thereof.

+ STATEMENT

Independent claims 1 and 43 have been amended to include the limitations that the substantially spherical or ellipsoidal body a) is formed of a material designed to maintain a tension load of at least about ten pounds without substantially deforming, and b) less than about 50% of the volume of the substantially spherical or ellipsoidal body constitutes one or more cavities.

1/5

FIG. 1

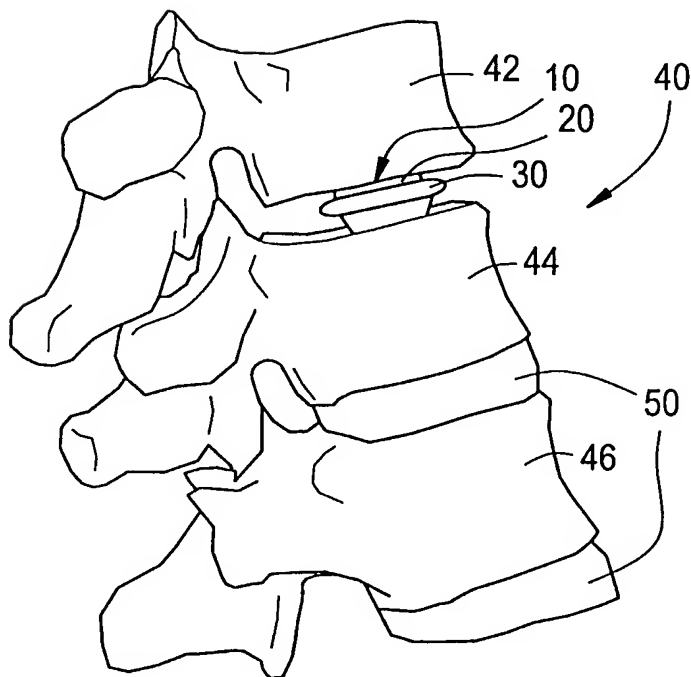
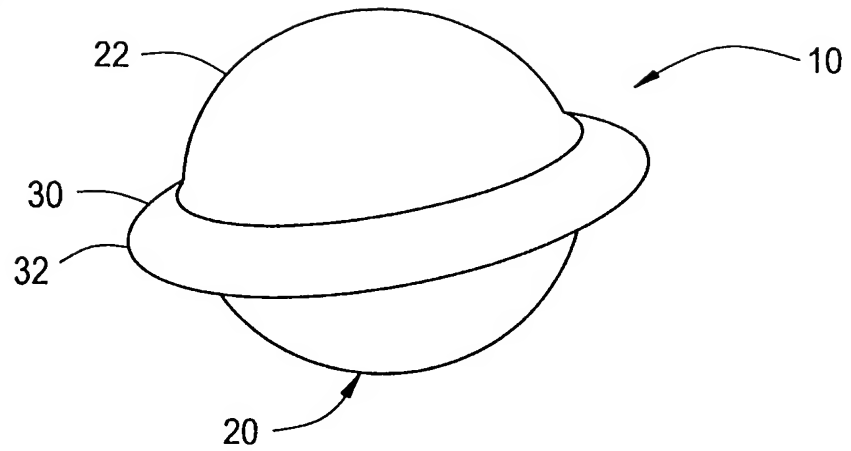


FIG. 2

2/5

FIG. 3

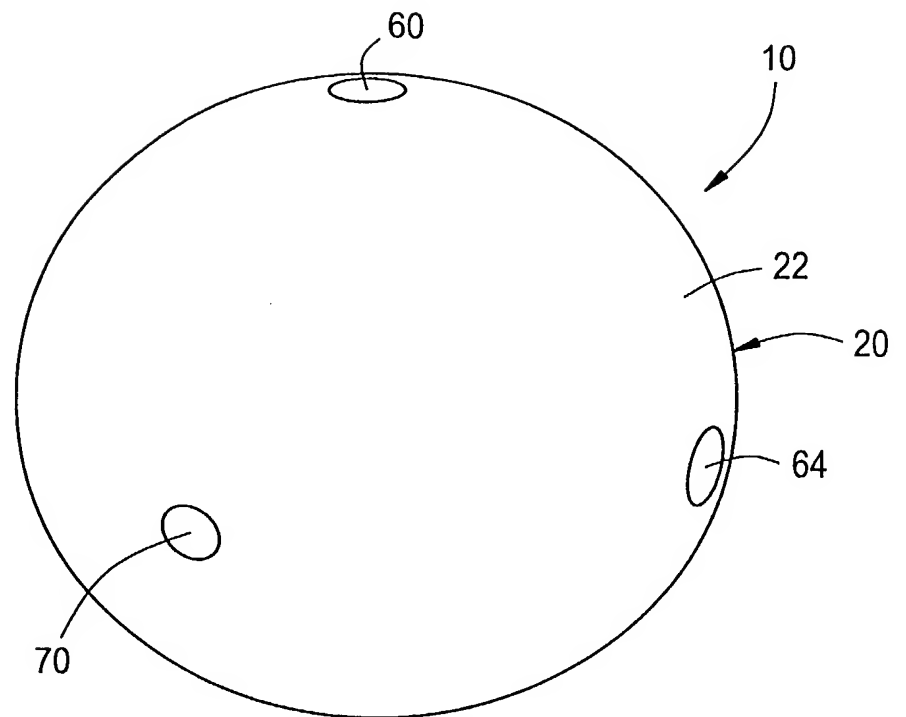
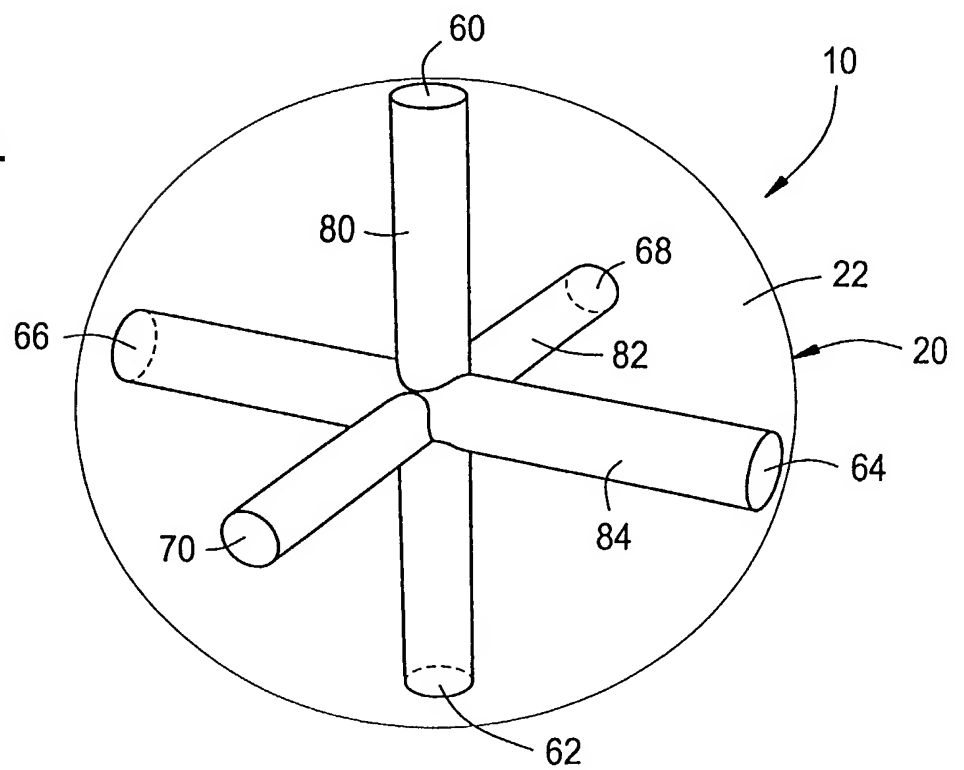


FIG. 4



3/5

FIG. 5

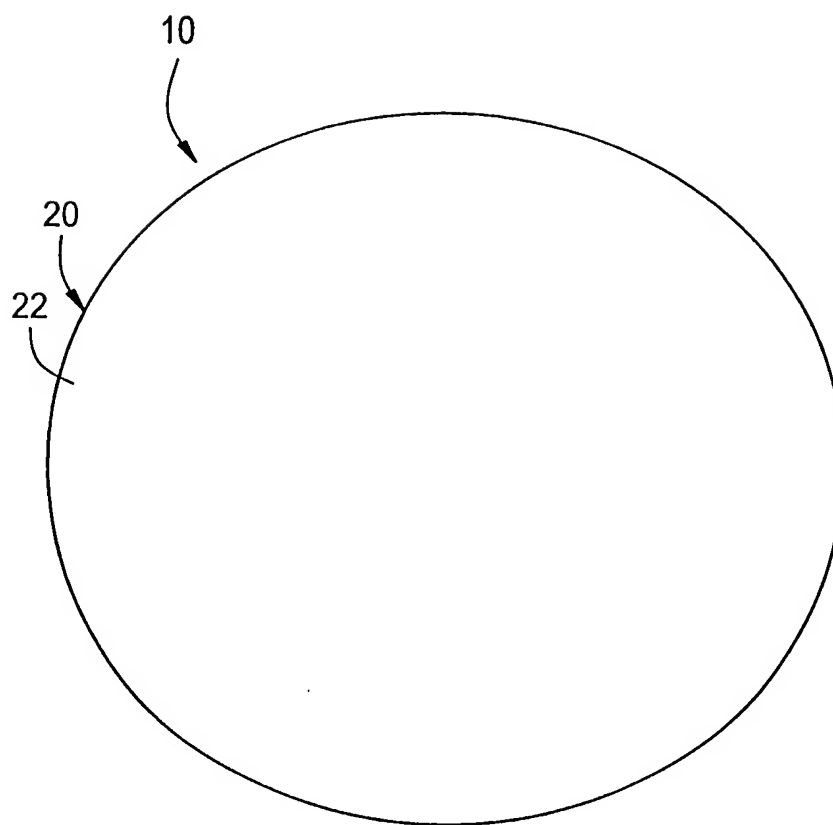
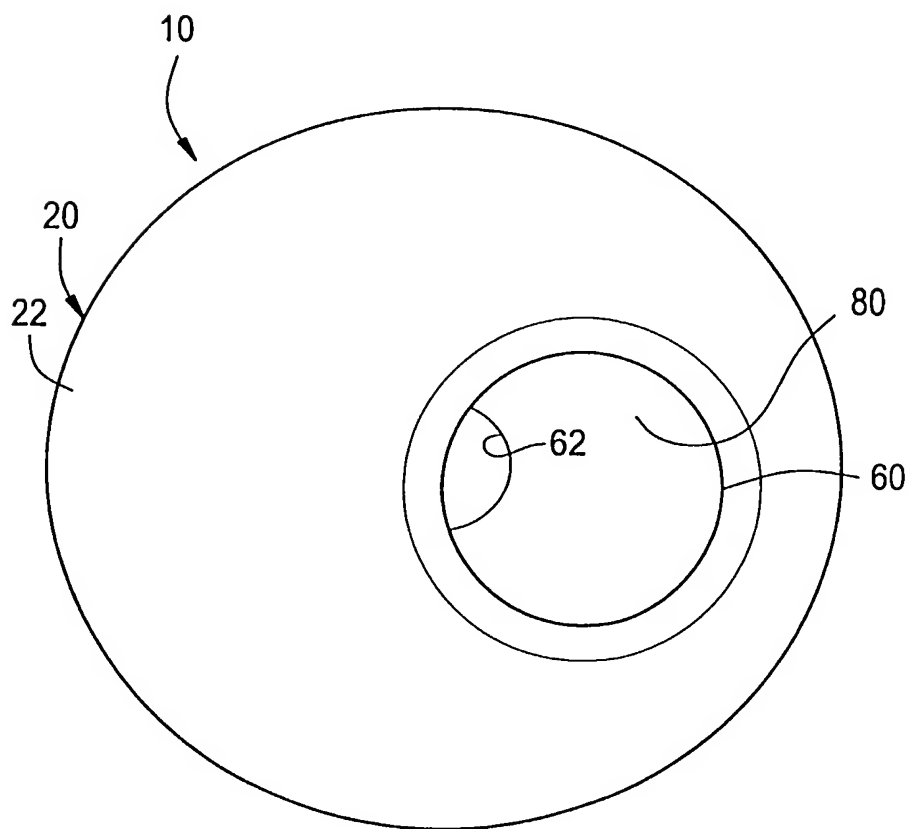


FIG. 6



4/5

FIG. 7

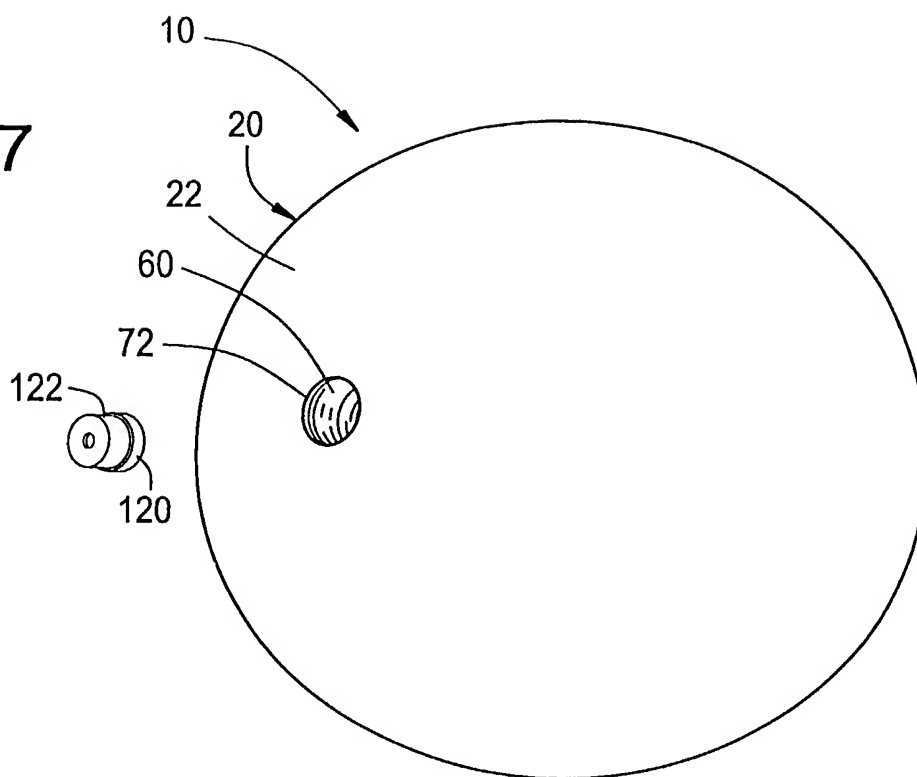
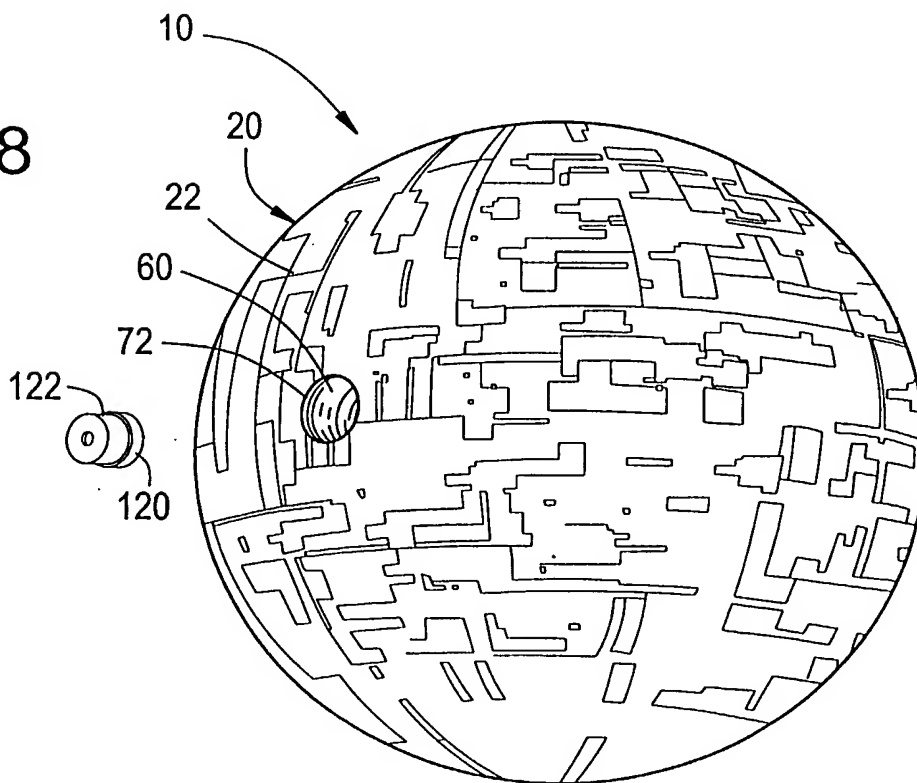


FIG. 8



5/5

FIG. 9

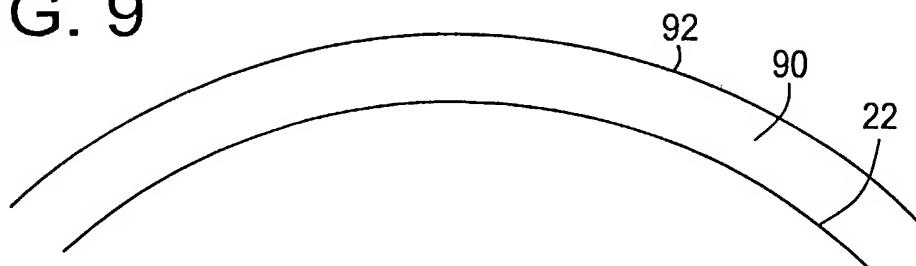


FIG. 10

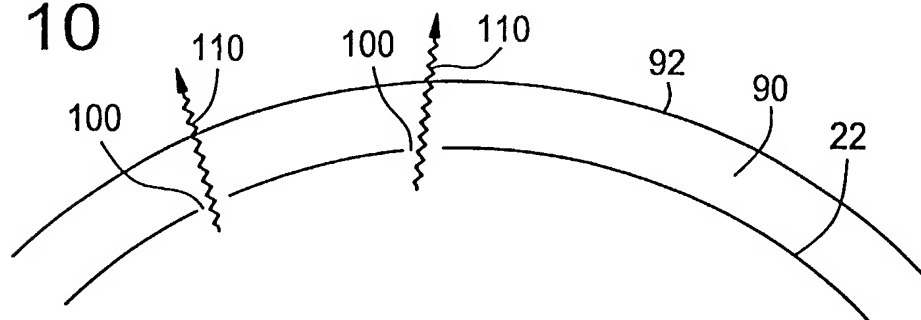


FIG. 11

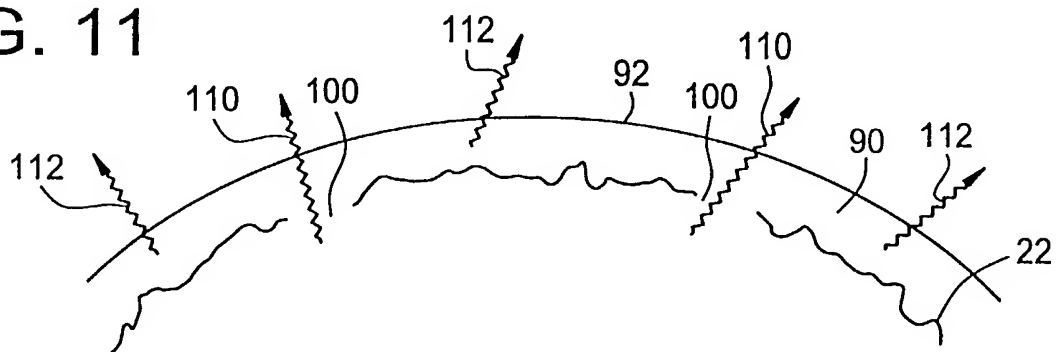
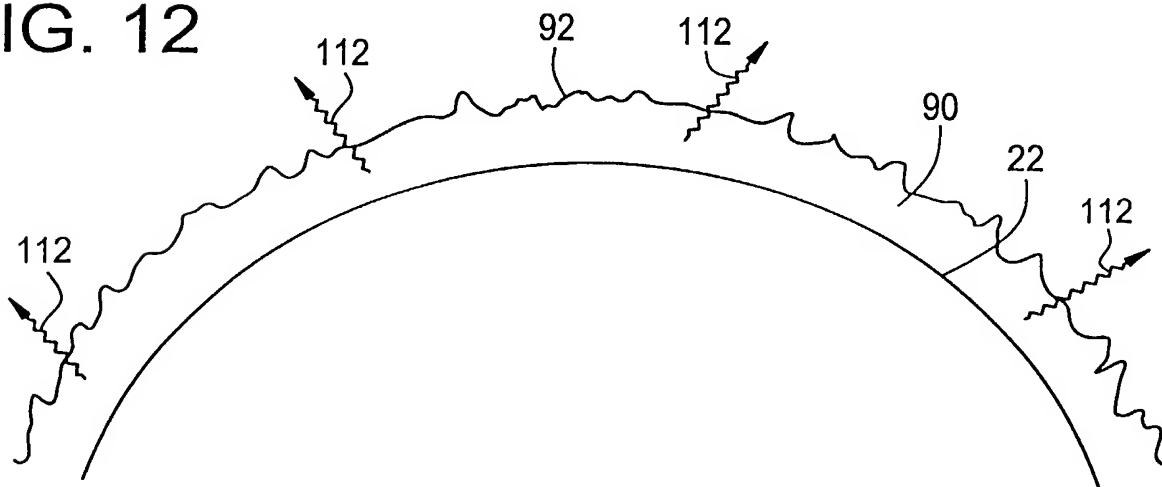


FIG. 12



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/07474

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 02/44

US CL : 623/17.14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.14, 16.11, 17.11, 17.16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	US 4,936,848 A (BAGBY) 26 JUNE 1990, ENTIRE DOCUMENT	1-14,23,25,51,52
Y		----- 15-22,24,26-50
X ---	US 5,674,296 A (BRYAN ET AL) 07 OCTOBER 1997, ENTIRE DOCUMENT	1,2,4,9,11,15,16, 18,19,21
Y		----- 17,20,22,24,26,4 6-50
Y	US 5,876,456 A (SEDERHOLM ET AL) 02 MARCH 1999, COL. 2 LINES 2-9 AND FIGURES.	27-50

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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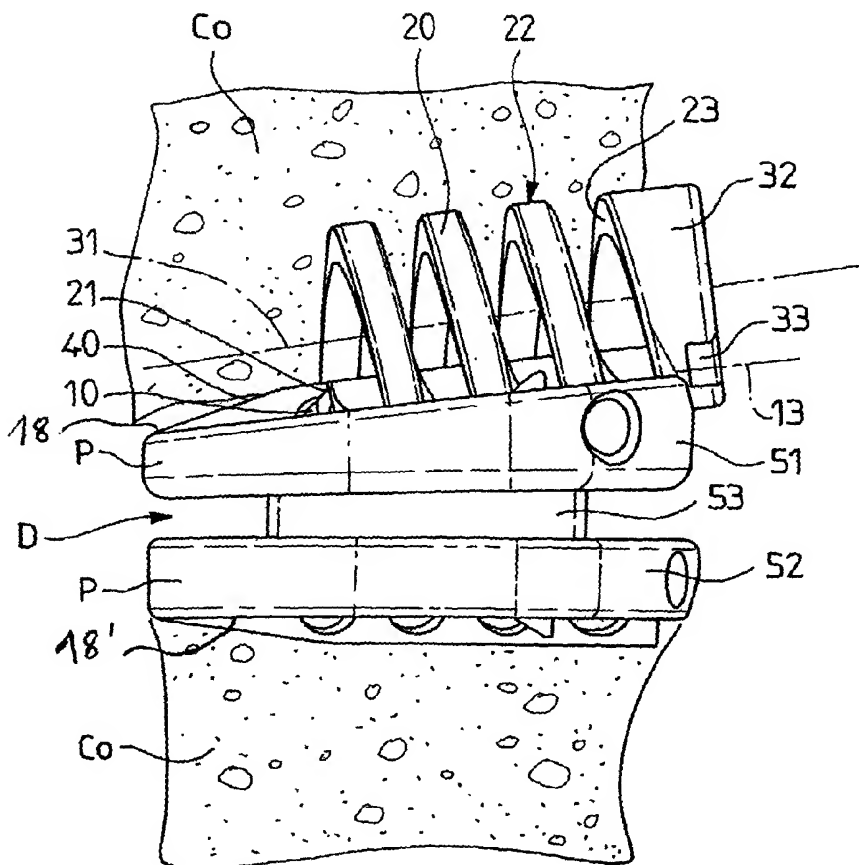
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[Suite sur la page suivante]

(54) Title: SYSTEM FOR FIXING A PART TO A BONE ELEMENT

(54) Titre : SYSTEME PERMETTANT DE FIXER UNE PIÈCE SUR UN CORPS OSSEUX



(57) Abstract: The invention relates to a system S which is used to fix a part P to a bone element Co. The invention is essentially characterised in that it consists of: at least one hole (10) which is disposed in part P; a rigid rod (20) comprising a first end (21), said rod being wound into a spiral (22) along a first helicoidal curve; and means (30) of rotating the rod (20) around the axis (31) of the first helicoidal curve, such that the first end (21) of the rod (20) moves alternatively inside and outside the bone element (Co) and, during the rotation thereof, the first end (21) of the rod (20) moves at least once into the opening (10). The invention is particularly suitable for fixing intervertebral discs (51, 52) or fusion cages to the vertebral bodies of two consecutive vertebrae.

(57) Abrégé : La présente invention concerne les systèmes S permettant de fixer une pièce P sur un corps osseux Co. Le système selon l'invention se caractérise essentiellement par le fait qu'il comporte au moins une percée 10 réalisée dans la pièce P, une tige rigide 20 comportant une première extrémité 21, la tige

[Suite sur la page suivante]

WO 03/068112 A1



HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) États désignés (régional) : brevet ARIPO (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), brevet eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), brevet européen (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Publiée :

- avec rapport de recherche internationale
- avant l'expiration du délai prévu pour la modification des revendications, sera republiée si des modifications sont reçues

En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

étant enroulée en spirale 22 selon une première courbe hélicoïdale, et des moyens 30 pour entraîner la rotation de la tige 20 autour de l'axe 31 de la première courbe hélicoïdale de façon que la première extrémité 21 de la tige 20 passe alternativement dans le corps Co et en dehors du corps, et que, dans son mouvement de rotation, la première extrémité 21 de la tige 20 passe au moins une fois dans la percée 10. Application, notamment, à la fixation des plateaux 51, 52 de disques intervertébraux, de cages intersomatiques, sur les corps vertébraux de deux vertèbres consécutives.

SYSTEME PERMETTANT DE FIXER UNE PIECE SUR UN CORPS OSSEUX

La présente invention concerne les systèmes permettant de fixer une pièce
5 sur un corps osseux, qui trouvent une application particulièrement avantageuse dans le domaine rachidien pour la fixation, par exemple, d'une cage intersomatique ou d'un disque intervertébral sur les corps vertébraux de deux vertèbres consécutives.

Il est déjà connu des prothèses intervertébrales qui sont implantées entre les
10 deux corps vertébraux de deux vertèbres. Ces prothèses comportent par exemple des plateaux qui doivent être respectivement fixés aux deux corps vertébraux.

En général, quand on veut fixer une pièce, par exemple métallique, sur un
corps osseux et que l'on veut que cette pièce soit immédiatement solidaire de ce
corps osseux, on utilise des vis ou analogues. Mais il arrive parfois que
l'emplacement de cette pièce par rapport au corps osseux sur lequel elle doit être
15 fixée ne permet pas l'utilisation de vis ou analogues, car il n'y a pas assez d'espace de recul devant la pièce par rapport au corps osseux pour pouvoir pré-positionner les vis avant de les visser dans le corps osseux en les passant préalablement par des lumières ou analogues réalisées dans la pièce.

En palliatif, sont utilisés des moyens comme des picots, nervures, etc. qui
20 sont ancrés dans la partie superficielle du corps osseux. En revanche, la solidarisation entre la pièce et le corps osseux ne peut dans ce cas se faire que par la repousse naturelle de l'os, c'est-à-dire par ostéosynthèse, en intercalant si nécessaire un produit favorisant cette ostéosynthèse, par exemple de l'hydroxy-apatite et/ou un métal biocompatible poreux ou non, ou analogue.

25 Cette dernière solution n'est pas pratique car il est dans ce cas nécessaire d'interdire au patient sur lequel est implantée une telle pièce de prothèse de ne pas avoir de mouvements importants tant que la solidification par ostéosynthèse n'est pas définitive.

La présente invention a donc pour but de réaliser un système permettant de
30 pallier les inconvénients rapportés ci-dessus des systèmes de l'art antérieur pour la fixation d'une pièce, par exemple métallique, sur un corps osseux, et qui trouvent une application particulièrement avantageuse dans les prothèses rachidiennes.

Plus précisément, la présente invention a pour objet un système permettant de fixer une pièce sur un corps osseux selon la revendication 1.

Ce système comporte :

- une tige comportant une première extrémité, ladite tige étant enroulée en spirale sensiblement selon une première courbe hélicoïdale par rapport à un axe longitudinal, et

5 - au moins une percée traversante réalisée dans ladite pièce et présentant une ligne axiale,

10 - des moyens pour entraîner la rotation de ladite tige autour de l'axe de ladite première courbe hélicoïdale de façon que la première extrémité de ladite tige passe alternativement dans le corps et en dehors du corps, et que, dans son mouvement de rotation, ladite première extrémité de la tige passe au moins une fois dans ladite percée traversante.

15 La pièce à fixer sur le corps osseux comporte, de préférence, une pluralité de percées traversantes, les lignes axiales de ces percées traversantes étant sensiblement perpendiculaires à l'axe longitudinal de la première courbe hélicoïdale, la section transversale des percées de cette dite pluralité de percées traversantes étant au moins égale à la section transversale maximale de ladite tige.

20 La ou les lignes axiales respectivement de la ou des percées traversantes est ou sont, soit droite(s) et sensiblement perpendiculaire(s) à l'axe longitudinal de la première courbe hélicoïdale, soit définie(s) sensiblement selon une seconde courbe hélicoïdale.

25 Ladite pièce à fixer comporte, de préférence, une nervure en saillie, la hauteur de ladite nervure, prise à partir des bords des dites percées traversantes, étant inférieure au diamètre intérieur de la spirale et cette nervure étant réalisée, de manière préférée, selon une ligne axiale sensiblement parallèle à l'axe longitudinal de la première courbe hélicoïdale.

 La section transversale de ladite tige peut avoir sensiblement la forme d'un quadrilatère rectangle, d'un cercle, ou tout autre forme.

30 Lesdites première et seconde courbes hélicoïdales sont, de préférence, sensiblement identiques et la ou les première et/ou seconde courbe(s) hélicoïdale(s) est ou sont, de préférence également, de pas constant.

 La ou les percée(s) traversante(s) comporte(nt), de préférence, chacune au moins une rampe bordant respectivement au moins une extrémité de chaque percée traversante pour guider le passage de la première extrémité de ladite tige dans lesdites percées.

Dans une variante, les moyens pour entraîner la rotation de la tige autour de l'axe de la première courbe hélicoïdale comportent une tête solidaire de la seconde extrémité de ladite tige, ladite tête comportant des moyens aptes à coopérer avec un ancillaire d'entraînement en rotation.

5 Dans cette variante, la tête présente, de préférence, une forme annulaire dont les diamètres intérieur et extérieur sont respectivement sensiblement égaux aux diamètres intérieur et extérieur de ladite spirale.

Le nombre de percées traversantes est, de préférence, sensiblement égal au nombre de spires de ladite spirale.

10 L'extrémité de la tige est, de préférence, pointue ou en biseau.

Dans une variante, ladite spirale présente une forme auto-taraudeuse.

La présente invention se rapporte également à une tige pour un système selon l'invention, à une cage intersomatique comportant au moins un système selon
15 l'invention et à un disque intervertébral artificiel comportant deux plateaux dont un au moins et de préférence les deux comporte(nt) un système selon l'invention.

Avantageusement, le système selon l'invention est simple et facile à fabriquer et à implanter. Il ne nécessite pas d'endommager d'une manière importante le corps
20 osseux.

De plus, le système selon l'invention est relativement simple à retirer lorsque cette opération est nécessaire.

D'autres caractéristiques et avantages de la présente invention apparaîtront
25 au cours de la description suivante donnée en regard des dessins annexés à titre illustratif mais nullement limitatif, dans lesquels :

- Les figures 1 et 2 représentent deux vues en coupe d'un mode de réalisation du système selon l'invention permettant de fixer une pièce sur un corps osseux, la figure 1 étant une coupe référencée I-I sur la figure 2, la figure 2 étant une coupe
30 référencée II-II sur la figure 1, et

- Les figures 3 et 4 représentent respectivement une vue en coupe et une vue en perspective cavalière, d'un autre mode de réalisation du système selon l'invention dans une application à la fixation des deux plateaux d'un disque intervertébral respectivement sur les deux corps vertébraux de deux vertèbres consécutives.

Il est précisé que, bien que les figures représentent plusieurs modes de réalisation de l'objet selon l'invention, les mêmes références y désignent les mêmes éléments, quelle que soit la figure sur laquelle elles apparaissent et quelle que soit la forme de représentation de ces éléments. De même, si des éléments ne sont pas spécifiquement référencés sur l'une des figures, leurs références peuvent être aisément retrouvées en se reportant à une autre figure.

La présente invention concerne un système S permettant de fixer une pièce P sur un corps osseux Co.

La pièce P comporte au moins une percée traversante 10 réalisée, par exemple, sur une surface extérieure 18, 18', cette percée traversante ayant une ligne axiale 10_x.

Le système S une tige rigide 20 comportant une première extrémité 21 conformée pour être apte à pénétrer dans le corps Co, la tige étant enroulée en spirale 22 sensiblement selon une première courbe hélicoïdale.

Le système comporte en outre des moyens 30 pour entraîner la rotation de la tige 20 autour de l'axe 31 de la première courbe hélicoïdale de façon que la première extrémité 21 de la tige 20 passe alternativement dans le corps Co et en dehors du corps, et que, dans son mouvement de rotation en dehors du corps Co, la première extrémité 21 de la tige 20, par exemple pointue ou en biseau, passe au moins une fois dans la percée traversante 10.

Il est précisé que la section transversale de la percée traversante 10 peut être circulaire et d'une section légèrement supérieure à la section maximale de la tige 20. Dans ce cas, la tige 20 ne passe qu'une seule fois dans cette percée. Mais il peut aussi être réalisé une percée de section transversale oblongue et de largeur au moins égale à la section maximale de la tige 20 et de longueur au moins égale à un multiple du pas de la spirale hélicoïdale 22. Dans ce cas, la première extrémité 21 de la tige passe, ou peut passer, plusieurs fois dans la même percée traversante.

Cette dernière réalisation est possible mais, de façon avantageuse, le système comporte une pluralité de percées traversantes 10, 11, 12, ..., comme illustré sur toutes les figures, réalisées dans la pièce P, présentant chacune respectivement une ligne axiale 10_x, 11_x, 12_x, ...

Dans une variante, les lignes axiales 10_x, 11_x, 12_x, ... de ces percées traversantes sont sensiblement définies selon une seconde courbe hélicoïdale, la section transversale des percées de cette pluralité étant au moins égale à la section transversale maximale de la tige 20 de façon que la tige puisse y coulisser
5 relativement aisément.

Dans une autre variante, les percées traversantes 10, 11, 12, ... sont réalisées dans la pièce P de façon que leurs lignes axiales 10_x, 11_x, 12_x, ... soient toutes sensiblement perpendiculaires à une même droite 13, elle-même parallèle à l'axe 31, pour favoriser la pénétration de la tige 20 dans l'os et l'aider à passer plus facilement
10 dans ces percées.

Pour favoriser la mise en place de la pièce P sur le corps Co et lui donner, dès sa mise en place, une première position relativement stable, il est avantageux que le système comporte en outre, comme illustré sur les figures, une nervure en saillie 40 réalisée sur la pièce P éventuellement apte à coopérer, par exemple par enfichage,
15 avec une rainure complémentaire préalablement réalisée dans le corps osseux Co. La hauteur de la nervure, prise à partir des bords des percées traversantes, est, bien entendu, inférieure au diamètre intérieur de la spirale 22.

En outre, de façon très préférentielle, la nervure 40 est réalisée selon une ligne axiale sensiblement parallèle à l'axe 31 et est sensiblement contenue dans un
20 plan défini par la droite 13 et l'axe 31 de la seconde courbe hélicoïdale en spirale 22.

Cette nervure 40 permet d'augmenter le maintien au niveau de la coopération entre les parois des percées traversantes et la spirale 22.

Dans une réalisation préférentielle qui facilite la réalisation de la spirale 22, la
25 section transversale de la tige 20 a sensiblement la forme d'un quadrilatère rectangle, par exemple un carré ou un rectangle, éventuellement d'un trapèze dont la grande base est peu différente de la petite et dont la forme peut alors s'apparenter à celle d'un rectangle.

Il est aussi précisé que les première et seconde courbes hélicoïdales définies
30 ci avant, sont avantageusement sensiblement identiques et ont de préférence un pas constant.

Dans le but de favoriser le guidage de la première extrémité 21 de la tige 20 lors de sa pénétration dans chaque percée traversante, la ou les percée(s) traversante(s) 10, 11, 12, ... comporte(nt) chacune au moins une rampe 14, 15

bordant respectivement au moins une extrémité 16, 17 de chaque percée traversante pour guider le passage de la première extrémité 21 de ladite tige 20 dans lesdites percées. Dans cette configuration, les lignes axiales 10_x , 11_x , 12_x , ..., tout en restant perpendiculaires à la droite 13, sont arrondies transversalement selon un rayon de courbure supérieure au rayon extérieur de la spirale 22, comme on peut le voir sur la figure 1.

Le système comporte de façon avantageuse des rampes 14, 15 bordant respectivement chacune des deux extrémités 16, 17 de chaque percée traversante.

Ces rampes, visibles sur les figures 2 et 4, adoptent la forme de portions de surface hélicoïdale en creux très voisine de celle de la surface extérieure de la spirale 22 définie auparavant.

Comme mentionné ci avant, le système comporte des moyens 30 pour entraîner la rotation de la tige 20 autour de l'axe 31 de la seconde courbe hélicoïdale. Ces moyens peuvent par exemple être constitués par la seconde extrémité 23 de la tige 20 en spirale 22. Cependant, il est préférable qu'ils comportent une tête 32 solidaire de cette seconde extrémité 23 de la tige 20, cette tête comportant des moyens 33 aptes à coopérer avec un ancillaire d'entraînement en rotation, par exemple équivalent à un tournevis, une clé à tube ou analogue.

Il est aussi très avantageux que la tête 32 présente une forme annulaire dont les diamètres intérieur et extérieur sont respectivement sensiblement égaux aux diamètres intérieur et extérieur de la spirale 22, ce qui permet d'obtenir une réalisation simultanée de la spirale 22 et de la tête 32, par usinage d'un tube cylindrique de révolution en titane ou analogue.

Cette réalisation de la tête de forme annulaire présente en outre un avantage lors de la mise en place de la spirale. En effet, la tête sert alors de butée pour définir la position limite de la spirale 22 par rapport à pièce P, comme illustré sur les figures 3 et 4.

Dans une réalisation possible préférentielle, le nombre de percées 10, 11, 12, ... est sensiblement égal au nombre de spires de la spirale 22, ce qui permet d'obtenir une relativement bonne fixation de la pièce P sur le corps osseux Co, avec une longueur minimale de spirale.

Le système selon l'invention peut être utilisé dans de nombreux domaines, mais trouve des applications particulièrement avantageuses pour les procédés de fixation de cages intersomatiques ou de disques intervertébraux.

Pour faciliter l'implantation du système selon l'invention, il peut être requis de réaliser au préalable un taraudage du corps osseux, afin de réaliser dans la paroi
une forme sensiblement hélicoïdale qui est exactement complémentaire de la forme
de la spirale 22. Cette opération est alors réalisée à l'aide d'un instrument de
taraudage.

Une fois le taraudage réalisé, la spirale de la prothèse est vissée dans le
taraudage.

Il est également possible d'utiliser une spirale auto-taraudante. Cela permet
d'éviter l'étape de taraudage préalable du corps osseux. La spirale (22) de la
prothèse est alors directement vissée dans le corps osseux.

Les figures 3 et 4 représentent, à titre illustratif, le système selon l'invention
utilisé pour fixer les deux plateaux 51, 52, d'un disque intervertébral artificiel D
coopérant entre eux par des moyens de rotule 53 ou analogue, avec respectivement
les deux corps vertébraux de deux vertèbres consécutives.

Le système de fixation tel que décrit ci-dessus fonctionne et s'utilise dans ce
cas de la façon suivante:

Quand il est nécessaire d'implanter, par exemple, un disque intervertébral
artificiel D entre deux corps vertébraux, on l'introduit en le glissant entre les deux
corps vertébraux, si nécessaire préalablement soumis à une légère distraction. Deux
tiges hélicoïdales en spirale 22 sont alors respectivement introduites comme décrit
auparavant en passant alternativement dans l'os des corps vertébraux et
respectivement dans les percées traversantes de chaque plateau du disque
intervertébral, la première extrémité 21 de chaque tige passant, à chaque tour
complet de la spirale lorsque la tige est entraînée en rotation par la tête 32, dans une
percée 10, 11, 12,

Sur les figures 1 et 4, la flèche 19 illustre le sens du mouvement de vissage
de la spirale 22 dans la structure vertébrale pour l'implantation du système S.

Le système selon l'invention s'utilisera de la même façon que décrit ci-dessus ,
pour fixer au moins l'une des deux surfaces extérieure opposées d'une cage
intersomatique sur au moins l'un des deux corps vertébraux de deux vertèbres

consécutives, les percées traversantes étant réalisées sur les faces opposées de la cage.

Le système de fixation décrit ci-dessus présente deux avantages primordiaux par rapport aux systèmes de l'art antérieur qui ne comportaient que des picots et/ou
5 nervures, avec éventuellement des produits favorisant l'ostéosynthèse entre les faces en regard venant en contact, respectivement des plateaux et des corps vertébraux.

Le premier de ces deux avantages est le fait qu'il est alors possible d'introduire le disque intervertébral ou la cage sans avoir à réaliser une distraction importante
10 entre les deux corps vertébraux, alors que, avec les systèmes de l'art antérieur, il était nécessaire de distraire les deux corps vertébraux d'au moins une valeur double de la hauteur des picots et/ou nervures.

Le second de ces deux avantages est le fait que la fixation permet d'obtenir ce que les techniciens appellent une stabilité primaire qui permet au patient d'effectuer
15 des mouvements qui ne lui étaient pas autorisés avec les systèmes de l'art antérieur qui l'obligeaient à attendre une consolidation osseuse importante, généralement de l'ordre de quelques semaines.

Pour l'ablation du système S, la spirale est simplement dévissée en tournant
20 la cage dans le sens inverse de la flèche 19. Il n'est pas nécessaire de casser le corps osseux pour libérer la spirale 22.

L'invention est décrite dans ce qui précède à titre d'exemple. Il est entendu que l'homme du métier est à même de réaliser différentes variantes de l'invention
25 sans pour autant sortir du cadre du brevet.

REVENDICATIONS

1. Système (S) permettant de fixer une pièce (P) sur un corps osseux (Co),
5 caractérisé en ce qu'il comporte:

- une tige (20) comportant une première extrémité (21), ladite tige (20) étant enroulée en spirale (22) sensiblement selon une première courbe hélicoïdale par rapport à un axe longitudinal (31), et

10 - au moins une percée traversante (10) réalisée dans ladite pièce (P) et présentant une ligne axiale (10_x),

- des moyens (30) pour entraîner en rotation ladite tige (20) autour de l'axe (31) de façon que la première extrémité (21) de ladite tige (20) passe alternativement dans le corps (Co) et en dehors du corps, et que, dans son mouvement de rotation, ladite première extrémité (21) de la tige (20) passe au moins une fois dans ladite
15 percée traversante (10).

2. Système selon la revendication 1, caractérisé en ce que ladite pièce (P) comporte une pluralité de percées traversantes (10, 11, 12, ...), les lignes axiales (10_x , 11_x , 12_x , ...) de ces percées traversantes étant sensiblement perpendiculaires à
20 l'axe longitudinal (31), la section transversale des percées de cette dite pluralité de percées traversantes (10, 11, 12, ...) étant au moins égale à la section transversale maximale de ladite tige (20).

3. Système selon la revendication 1 ou la revendication 2, caractérisé en ce
25 que la ou les lignes axiales (10_x , 11_x , 12_x , ...) respectivement de la ou des percées traversantes (10, 11, 12, ...) est ou sont droite(s) et sensiblement perpendiculaire(s) à l'axe (31).

4. Système selon l'une quelconque des revendications 1 à 3, caractérisé en ce
30 que la ou les lignes axiales (10_x , 11_x , 12_x , ...) respectivement de la ou des percées traversantes (10, 11, 12, ...) est ou sont définie(s) sensiblement selon une seconde courbe hélicoïdale.

5. Système selon l'une quelconque des revendications 1 à 4, caractérisé en ce que ladite pièce (P) comporte une nervure en saillie (40), la hauteur de ladite nervure, prise à partir des bords des dites percées traversantes, étant inférieure au diamètre intérieur de la spirale (22).

5

6. Système selon la revendication 5, caractérisé en ce que ladite nervure (40) est réalisée selon une ligne axiale sensiblement parallèle à l'axe (31).

10

7. Système selon l'une quelconque des revendications 1 à 6, caractérisé en ce que la section transversale de ladite tige (20) a sensiblement la forme d'un quadrilatère rectangle.

15

8. Système selon l'une quelconque des revendications 1 à 6, caractérisé en ce que la section transversale de ladite tige (20) a sensiblement la forme d'un cercle.

9. Système selon l'une quelconque des revendications 4 à 8, caractérisé en ce que lesdites première et seconde courbes hélicoïdales sont sensiblement identiques.

20

10. Système selon l'une quelconque des revendications 1 à 9, caractérisé en ce que la ou les première et/ou seconde courbe(s) hélicoïdale(s) est ou sont de pas constant.

25

11. Système selon l'une quelconque des revendications 1 à 10, caractérisé en ce que la ou les percée(s) traversante(s) (10, 11, 12, ...) comporte(nt) chacune au moins une rampe (14, 15) bordant respectivement au moins une extrémité (16, 17) de chaque percée traversante pour guider le passage de la première extrémité (21) de ladite tige (20) dans lesdites percées.

30

12. Système selon l'une quelconque des revendications 1 à 11, caractérisé en ce que les moyens (30) pour entraîner la rotation de la tige (20) autour de l'axe (31) de la première courbe hélicoïdale comportent une tête (32) solidaire de la seconde extrémité (23) de ladite tige (20), ladite tête comportant des moyens (33) aptes à coopérer avec un ancillaire d'entraînement en rotation.

13. Système selon la revendication 12, caractérisé en ce que la tête (32) présente une forme annulaire dont les diamètres intérieur et extérieur sont respectivement sensiblement égaux aux diamètres intérieur et extérieur de ladite spirale (22).

5

14. Système selon l'une quelconque des revendications 1 à 13, caractérisé en ce que l'extrémité (21) de la tige (20) est pointue ou en biseau.

10

15. Système selon l'une quelconque des revendications 1 à 14, caractérisé en ce que le nombre de percées traversantes (10, 11, 12, ...) est sensiblement égal au nombre de spires de ladite spirale (22).

15

16. Système selon l'une quelconque des revendications 1 à 15, caractérisé en ce que ladite spirale (22) présente une forme auto-taraudeuse.

20

17. Tige (20) pour un système (S) selon l'une quelconque des revendications 1 à 16, caractérisée en ce que ladite tige (20) comporte une première extrémité (21), ladite tige (20) étant enroulée en spirale (22) sensiblement selon une première courbe hélicoïdale par rapport à un axe longitudinal (31).

25

18. Cage intersomatique comportant au moins un système (S) selon l'une quelconque des revendications 1 à 16, caractérisée en ce que ladite cage comporte au moins une percée traversante (10) et de préférence plusieurs percées traversantes (10, 11, 12, ...).

30

19. Disque intervertébral artificiel (D) comportant deux plateaux (51, 52) et au moins un système (S) selon l'une quelconque des revendications 1 à 16, caractérisé en ce qu'au moins un plateau (51, 52), et de préférence les deux x (51, 52), comporte(nt) chacun au moins une percée traversante (10) et de préférence plusieurs percées traversantes (10, 11, 12, ...).

1/2

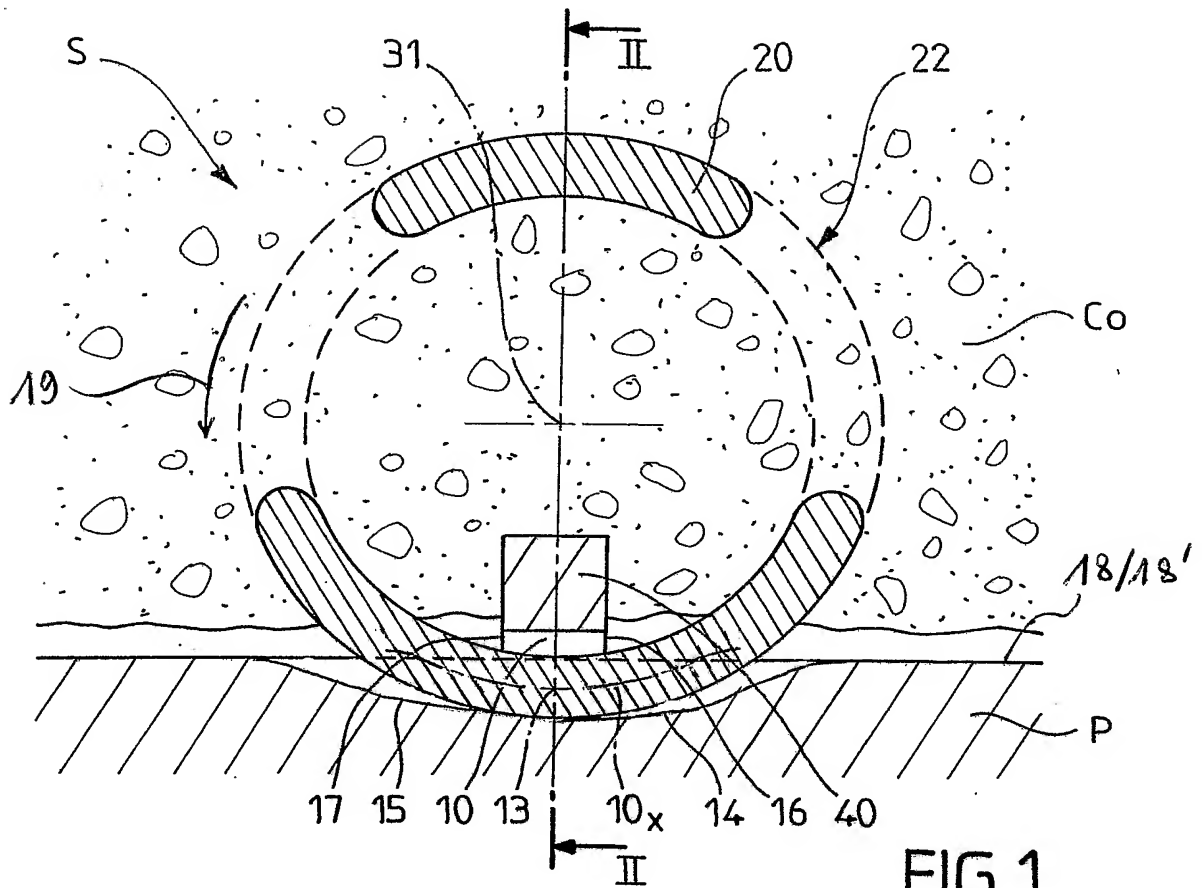


FIG. 1

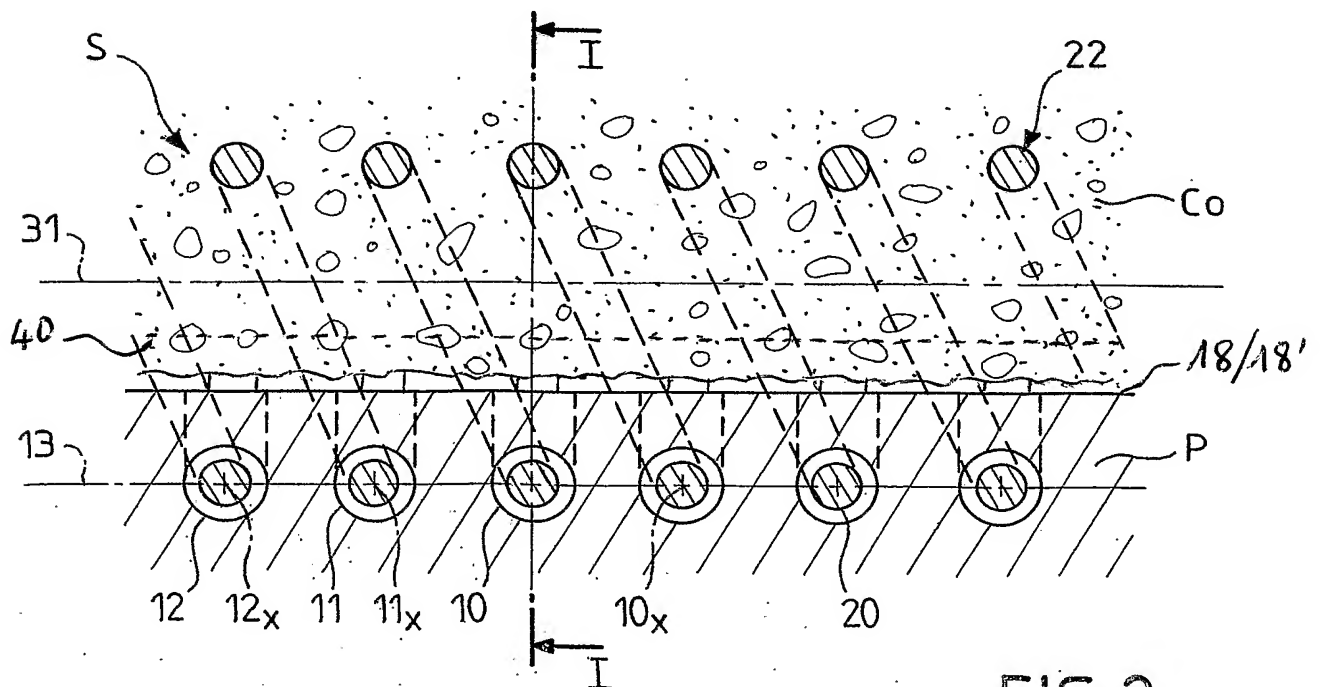


FIG. 2

2/2

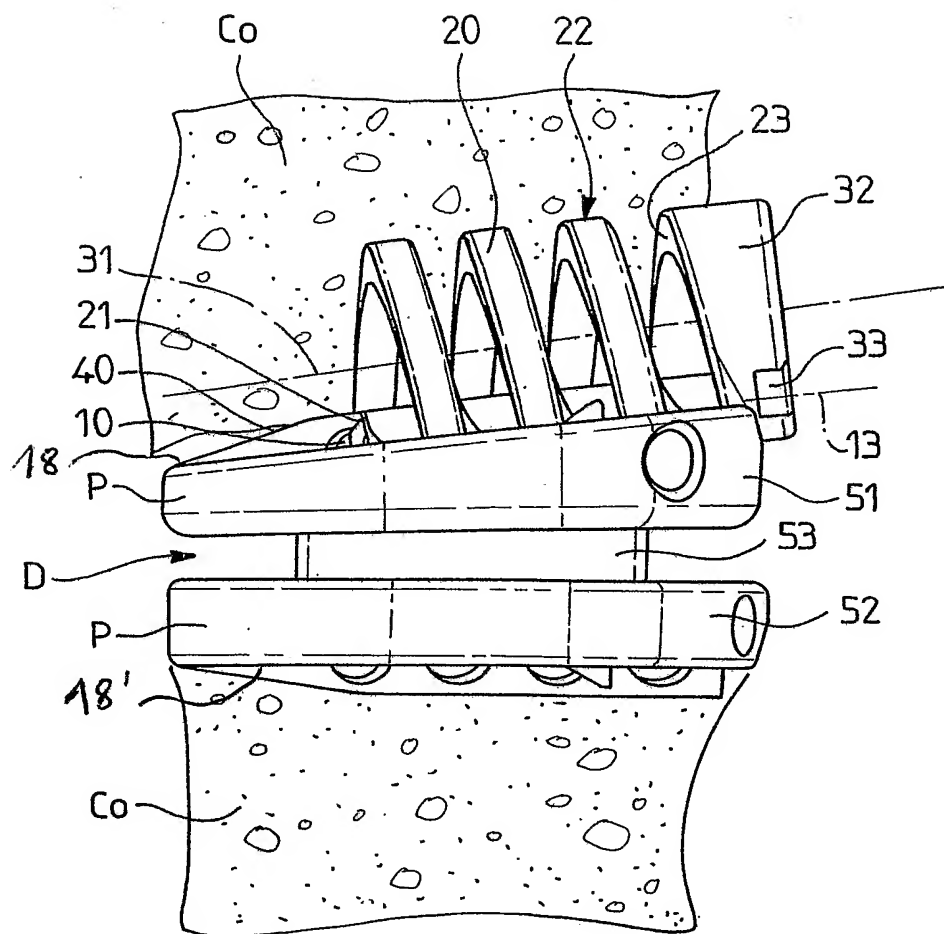


FIG. 3

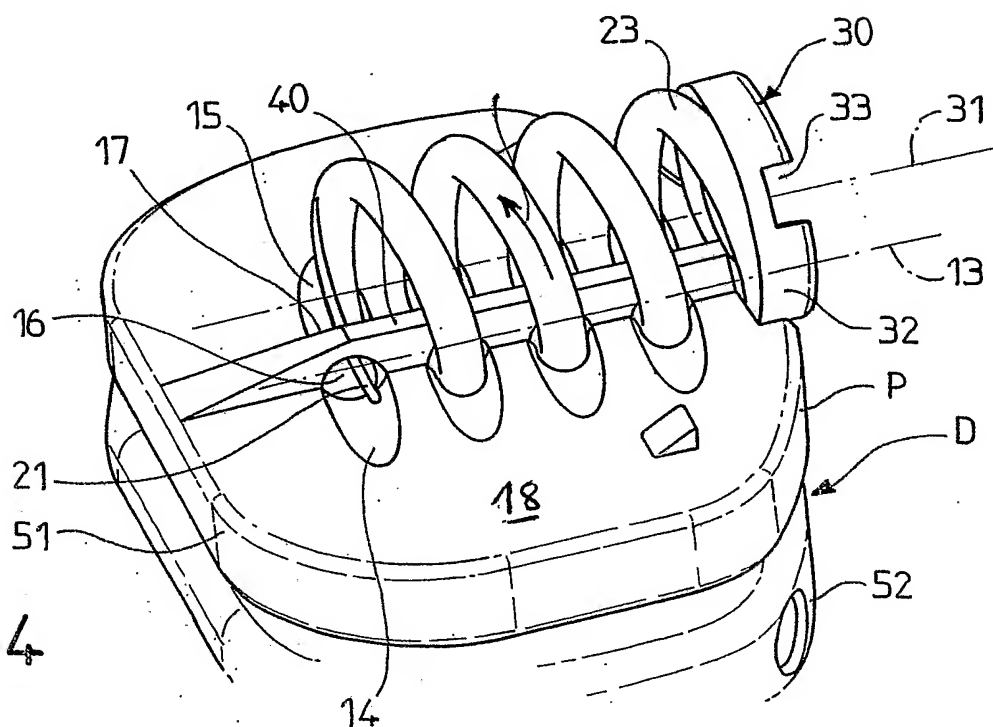


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No

PCT/FR 03/00438

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 02117 A (AESCULAP AG & CO KG ;EISEN GUNTMAR (DE); SCHULTZ ROBERT (DE); WING) 22 January 1998 (1998-01-22) claims 1,3,4; figures ---	1-4, 7-16,18, 19
A	WO 98 48738 A (CROZET YVES ;DIMSO SA (FR)) 5 November 1998 (1998-11-05) claims 1,12; figures 38-40 ---	1-4, 7-16,18, 19
A	US 5 263 953 A (BAGBY GEORGE W) 23 November 1993 (1993-11-23) figures ---	1
A	US 5 423 817 A (LIN CHIH-I) 13 June 1995 (1995-06-13) figures ---	1
	--- -/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

21 July 2003

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/FR 03/00438

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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International Application No

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A. CLASSEMENT DE L'OBJET DE LA DEMANDE

CIB 7 A61F2/44

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)

CIB 7 A61F

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)

EPO-Internal

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie °	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	WO 98 02117 A (AESCULAP AG & CO KG ;EISEN GUNTMAR (DE); SCHULTZ ROBERT (DE); WING) 22 janvier 1998 (1998-01-22) revendications 1,3,4; figures ---	1-4, 7-16,18, 19
A	WO 98 48738 A (CROZET YVES ;DIMSO SA (FR)) 5 novembre 1998 (1998-11-05) revendications 1,12; figures 38-40 ---	1-4, 7-16,18, 19
A	US 5 263 953 A (BAGBY GEORGE W) 23 novembre 1993 (1993-11-23) figures ---	1
A	US 5 423 817 A (LIN CHIH-I) 13 juin 1995 (1995-06-13) figures --- -/--	1

☒ Voir la suite du cadre C pour la fin de la liste des documents☒ Les documents de familles de brevets sont indiqués en annexe

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- *&* document qui fait partie de la même famille de brevets

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C.(suite) DOCUMENTS CONSIDERES COMME PERTINENTS		
Catégorie °	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	FR 2 812 188 A (SPINEVISION S A) 1 février 2002 (2002-02-01) revendications 1-5; figures 1-4 ----	1
A	US 4 038 703 A (BOKROS JACK C) 2 août 1977 (1977-08-02) revendications 1,5,13; figures 1-7 -----	1

RAPPORT DE RECHERCHE INTERNATIONALE

Demande Internationale No

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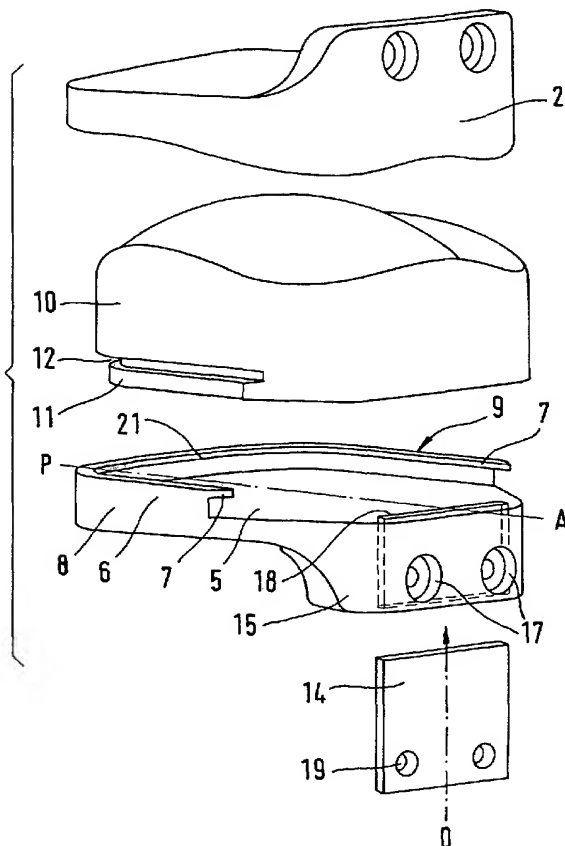
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[Fortsetzung auf der nächsten Seite]

(54) Title: INTRAVERTEBRAL PROSTHESIS

(54) Bezeichnung: ZWISCHENWIRBELPROTHESE



(57) Abstract: The invention relates to an intravertebral prosthesis, in particular for the cervical vertebral column, essentially comprising a first cover plate (1), for connection to a first vertebral body, a second cover plate (2), for connection to a second vertebral body and a prosthesis centre (10), which forms a joint with the second cover plate (2). The prosthesis centre (10) is held by a seat (9, 5) in the first cover plate (1), embodied as a guide device (7, 11, 12). The centre (10) may be inserted into the guide device from the ventral side in the AP direction (A) relative to the first cover plate (1). A stop plate (14) is provided on the ventral edge of the first cover plate which may be displaced in a sliding guide (18), between a locking and a non-locking position.

(57) Zusammenfassung: Zwischenwirbelprothese, insbesondere für die Halswirbelstule, die im wesentlichen aus einer ersten mit einem ersten Wirbelkörper zu verbindenden Deckplatte (1), einer zweiten mit dem zweiten Wirbelkörper zu verbindenden Deckplatte (2) und einem Prothesenkern (10) besteht, der mit der zweiten Deckplatte (2) ein Gelenk bildet. Der Prothesenkern (10) wird von einem Sitz (9, 5) der ersten Deckplatte (1) gehalten, der als Führungseinrichtung (7, 11, 12) ausgebildet ist. Der Kern (10) ist relativ zur ersten Deckplatte (1) von der ventralen Seite her in AP-Richtung (A) in die Führungseinrichtung einschiebbar. Am ventralen Rand der ersten Deckplatte ist eine Anschlagplatte (14) vorgesehen. Diese ist in einer Gleitführung (18) zwischen einer sperrenden und einer nicht sperrenden Stellung verschiebbar.

WO 03/075803 A1



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Erklärungen gemäß Regel 4.17:

- hinsichtlich der Identität des Erfinders (Regel 4.17 Ziffer i) für alle Bestimmungsstaaten
- hinsichtlich der Berechtigung des Anmelders, ein Patent zu beantragen und zu erhalten (Regel 4.17 Ziffer ii) für alle Bestimmungsstaaten

Veröffentlicht:

- mit internationalem Recherchenbericht
- mit geänderten Ansprüchen

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

5

Zwischenwirbelprothese

10

Zwischenwirbelprothesen dienen dem Ersatz der Bandscheibe. Sie bestehen aus zwei Deckplatten, deren Außenflächen zur Verbindung mit benachbarten Wirbelkörpern ausgebildet sind, und einer von den Deckplatten eingeschlossenen Gelenkeinrichtung. Bei einem bekannten Prothesentyp (WO 01/01893, FR-A-2718635) bildet die obere Deckplatte eine konkav-sphärische Gelenkfläche auf ihrer Innenseite, die mit der konvex-sphärischen Oberseite eines aus Polyethylen bestehenden Prothesenkerns zur Bildung eines Gelenks zusammenwirkt. Die flache Unterseite und der Rand des Kerns sind passend in einem Sitz aufgenommen, der von der unteren Deckplatte gebildet ist. Dieser Sitz besteht aus einer ebenen Bodenfläche und einem diese an drei Seiten (seitlich und dorsal) umgebenden, hochstehenden Rand. An den Seiten wird der Rand von zwei sich im wesentlichen in AP-Richtung erstreckenden, hinterschnittenen Randleisten gebildet, denen komplementär vorspringende Leisten bzw. Nuten am Rand des Prothesenkerns entsprechen. An der ventralen Seite ist der Rand der Deckplatte offen, so daß der Prothesenkern schubladenartig in einer in AP-Richtung verlaufenden Bewegung in den Rand der Deckplatte eingeschoben werden kann. Im eingeschobenen Zustand ist der Prothesenkern durch die zusammenwirkenden vorspringenden Leisten und Nuten der Deckplatte und des Prothesenkerns gegen Abheben gesi-

chert. Insbesondere kann er sich aus der vorgesehenen Position nicht dorsal zum Rückenmark hin entfernen wenn die Deckplatten sich bei einer Beugebewegung dorsal aufspreizen.

5 Es gibt bekannte Zwischenwirbelprothesen, bei denen der Rand der unteren Deckplatte auch ventral geschlossen ist (EP-B-471821, US-A-5425773). Jedoch hat dies den Nachteil, daß der Prothesenkern entweder nach dem Einsetzen der Deckplatten nicht zwischen diese eingefügt werden kann oder im Sitz der
10 unteren Deckplatte nicht gegen Abheben gesichert ist. Die Erfindung bezieht sich dagegen ausschließlich auf denjenigen Prothesentyp, bei welchem der Sitz der unteren Deckplatte als ventral offene Einschubführung für den Prothesenkern ausgebildet ist, damit er nach der Implantation der Deckplatten in
15 die Prothese eingefügt werden kann.

Damit der Prothesenkern nicht ventral aus dem Sitz entweichen kann, ist bei dem bekannten Prothesen dieser Art ein Rastanschlag vorgesehen (FR-A-2 718 635, WO 01/01893). Dieser besteht aus zusammenwirkenden Vorsprüngen und Ausnehmungen in
20 der Unterseite des Prothesenkerns einerseits und der Bodenfläche des Sitzes andererseits. Damit diese beim Einschieben des Prothesenkerns in den Sitz in Eingriff miteinander gelangen können, muß der aus nachgiebigen Kunststoffmaterial bestehende Sitz sich vor dem Verrasten dieser Elemente elastisch verformen. Dies hat den Nachteil, daß die Verrastung
25 prinzipiell unsicher ist, weil sie durch eine entsprechende elastische Verformung des Prothesenkerns wieder gelöst werden kann. Zwar kann man die Rastsicherheit erhöhen, indem man dem
30 Prothesenkern einen größtmöglichen Verformungswiderstand abverlangt. Aber dadurch wird dem Operateur das Einschieben des Prothesenkerns in den Sitz erschwert. Auch kann es geschehen,

daß die Rastelemente aus zufälligen Gründen, die dem Operateur verborgen bleiben, die Raststellung nicht oder nicht vollständig erreichen, weil z.B. in der Rastausnehmung ein Fremdkörper verblieben ist oder weil der Prothesenkern wegen
5 eines zufälligen Hindernisses nicht weit genug in den Sitz hineingeschoben wurde.

Der Erfindung liegt somit die Aufgabe zugrunde, eine Zwischenwirbelprothese des geschilderten Typs zu schaffen, bei
10 welcher der Prothesenkern sicher in der Prothese gehalten ist und die Operation nicht erschwert wird.

Die erfindungsgemäße Lösung findet sich in der Merkmalskombination des Anspruchs 1.

15

Um dem Prothesenkern die AP-Bewegung zu gestatten, die für das Einschieben in den Sitz erforderlich ist, ist der Sitz als Führungseinrichtung mit einer in AP-Richtung verlaufenden Richtung ausgebildet. Diese kann von einander gegenüberliegenden, parallelen, seitlichen Führungsschienen gebildet
20 sein, zwischen denen der Kern so gehalten ist, daß er sich lediglich in AP-Richtung bewegen kann. Dabei sind die Führungsschienen zweckmäßigerweise hinterschnitten, um mit einer in den Hinterschnitt eingreifenden Leiste des Kerns zusammenzuwirken. Auf diese Weise wird verhindert, daß der Kern sich
25 von der ihn haltenden Deckplatte abhebt. Dies hat den Vorteil, daß die für die Eingrenzung der Kernbewegung vorgesehenen Einrichtungen nicht sehr hoch sein müssen und daher auch keine Gefahr besteht, daß sie die Relativbewegung der Deckplatten im Verhältnis zueinander behindern könnten. Damit der
30 Kern nicht dorsal oder ventral aus dem Führungsbereich der Schienen herausgleitet, sind entsprechende Anschläge vorgese-

hen. Der dorsale Bewegungsanschlag ist zweckmäßigerweise starr mit der den Sitz (d.h. die Führungsschienen) bildenden Deckplatte verbunden. Auf der ventralen Seite ist ein Bewegungsanschlag vorgesehen, der aus seiner sperrenden Stellung
5 entfernenbar ist, damit man den Kern nach der Implantation der Deckplatte leichter einsetzen kann. Anschließend wird der Anschlag in der Stellung fixiert, in der er das Entweichen des Kerns verhindert.

10 Am ventralen Rand der den Sitz bildenden Deckplatte ist eine Gleitführung vorgesehen, in oder an welcher der Anschlag zwischen einer sperrenden Stellung und einer nicht sperrenden Stellung verschiebbar ist. Dadurch ist die Voraussetzung dafür geschaffen, daß der Operateur den Anschlag bewußt in die
15 sperrende Stellung verbringen muß. Die sperrende Stellung des Anschlags wird daher mit Sicherheit erreicht.

Besonders zweckmäßig ist eine Ausführungsform, bei welcher die Gleitführung von einem quer zur Führungseinrichtung verlaufenden Führungsschlitz gebildet ist, der den als Anschlag-
20 platte ausgebildeten Anschlag aufnimmt.

Beispielsweise kann der Führungsschlitz eine quer zur Erstreckungsebene der Deckplatte verlaufende Führungsrichtung
25 haben. D.h. daß die Anschlagplatte in ihrer sperrenden Stellung zu einem Teil in dem Schlitz steckt und von diesem gehalten wird und zu einem anderen Teil über die Bodenfläche des Sitzes hinausragt, um den Prothesenkern in dem Sitz festzuhalten. In der nicht sperrenden Stellung ist sie unter die
30 Bodenfläche des Sitzes in den Schlitz abgesenkt oder aus diesem gänzlich nach unten oder oben entfernt.

Statt dessen kann der Führungsschlitz auch eine parallel zur Erstreckungsebene der ersten Deckplatte und quer zur AP-Richtung verlaufende Führungsrichtung haben. In diesem Fall wird die Anschlagplatte von der Seite her in den Führungsschlitz eingeschoben, um in die sperrende Stellung zu gelangen.

In jedem Fall sollten Sicherungseinrichtungen vorhanden sein, die die Anschlagplatte in der sperrenden Stellung festhalten. Eine besonders zuverlässige Sicherung besteht darin, daß die Anschlagplatte von einer Befestigungsschraube durchquert ist, so daß sich die Anschlagplatte aus der Sicherungsstellung nur dann entfernen kann, wenn zuvor die Schraube entfernt wurde. Zu diesem Zweck wird der Führungsschlitz von wenigstens einem Schraubenloch durchquert und weist die Anschlagplatte ein in ihrer sperrenden Stellung damit fluchtendes Schraubenloch auf. Diese Ausführung ist insbesondere dann vorteilhaft, wenn der Führungsschlitz in einem Befestigungsflansch liegt, der am ventralen Rand der den Sitz bildenden Deckplatte vorgesehen ist.

Eine weitere Sicherung, durch die die Anschlagplatte gegen ein Entweichen aus dem Führungsschlitz gesichert wird, besteht darin, daß der Prothesenkern einen Teil aufweist, der die im Führungsschlitz enthaltene Anschlagplatte überdeckt. Diese Überdeckung kann als ein Schlitz im Prothesenkern ausgebildet sein, der mit dem Führungsschlitz fluchtet, wenn der Prothesenkern die vorgesehene Stellung im Sitz erreicht hat. Der Führungsschlitz in der Deckplatte einerseits und der damit fluchtende Schlitz im Prothesenkern andererseits bilden

dann eine Aufnahme für die Anschlagplatte, in die sie leicht von der Seite eingeschoben werden kann.

5 Eine weitere Sicherungsmöglichkeit besteht darin, daß die Anschlagplatte eine in der sperrenden Stellung in der Richtung des Führungsschlitzes über den Führungsschlitz hinausragende, leicht umbiegbare Sicherungsnase aufweist. Diese wird vom Operateur nach dem Einsetzen so verbogen, daß sie aus der Ebene der Anschlagplatte herausragt und dadurch die Rückbewe-
10 gung im Führungsschlitz unmöglich macht.

Bei einer anderen erfindungsgemäßen Ausführung der Anschlagplatte wird diese nicht translatorisch aus der nicht sperrenden Stellung in die sperrende Stellung überführt, sondern
15 durch eine Schwenkbewegung. In diesem Falle wird die Gleitführung, die die Anschlagplatte aufnimmt von einer am ventralen Rand der Deckplatte quer zur AP-Richtung verlaufenden Gleitführungsfläche und einem sich davon erhebenden Schwenkbolzen gebildet, auf dem die Anschlagplatte schwenkbar gelagert ist. Die Anschlagplatte weist eine Zunge auf, die in ei-
20 ner sperrenden Schwenkstellung der Anschlagplatte über die Bodenfläche des Sitzes hinausragt und damit das Entweichen des Prothesenkerns aus dem Sitz hindert. In der nicht sperrenden Stellung ist diese Anschlagzunge unter die Bodenfläche des Sitzes abgesenkt. Die Gleitführungsfläche, an der die An-
25 schlagplatte gehalten ist, wird zweckmäßigerweise von der Stirnfläche eines Befestigungsflanschs gebildet. Dieser enthält auch mindestens ein Schraubenloch in der Nachbarschaft des Schwenkbolzens. Die Anschlagplatte kann erfindungsgemäß
30 zur Sicherung der in diesem Schraubenloch befindlichen Schraube genutzt werden, indem sie mit einem Flügel über den in dem Schraubenloch befindlichen Schraubenkopf greift.

Der erfindungsgemäße Anschlag ist nicht nur für diejenigen Fälle geeignet, in denen der Prothesenkern eine feste unbewegliche Stellung im Sitz einnimmt, sondern auch für diejenigen Fälle, in denen ihm Bewegungsfreiheit, insbesondere in AP-Richtung gegeben ist. Die von dem Sitz gebildete Führungseinrichtung für den Prothesenkern wird dann nicht nur für dessen Einschubbewegung genutzt sondern auch für eine ständige Beweglichkeit. Diese kann vorteilhaft sein, insbesondere bei Zervikalprothesen, bei denen die Gelenkfläche des Prothesenkerns sich über im wesentlichen die gesamte Deckplatte erstreckt. In diesen Fällen möchte man nämlich den Krümmungsradius der Gelenkfläche gering halten, um die Bauhöhe der Prothese gering zu halten. In solchen Fällen kann eine AP-Beweglichkeit des Prothesenkerns die Annäherung der Beugeeigenschaften der Prothese an die natürlichen Verhältnisse verbessern. Ein besonderer Aspekt des Erfindungsgedankens besteht deshalb darin, daß innerhalb eines Systems von Zwischenwirbelprothesen neben solchen, die diese AP-Beweglichkeit aufweisen, andere Prothesen mit vorzugsweise übereinstimmender Außenform vorhanden sind, die keine AP-Beweglichkeit zwischen dem Prothesenkern und der ihn haltenden Deckplatte zeigen. Dies ermöglicht es dem Arzt, intraoperativ zu entscheiden, ob er AP-Beweglichkeit vorsehen will oder nicht. Zweckmäßigerweise sind die Deckplatten der in AP-Richtung beweglichen bzw. unbeweglichen Prothesen übereinstimmend geformt und ist lediglich der Kern unterschiedlich. Es kann aber auch vorgesehen sein, daß der Prothesenkern und die mit ihm das Gelenk bildende Deckplatte in allen Typen übereinstimmen, während die AP-Beweglichkeit durch Unterschiedlichkeit der den Prothesenkern haltenden Deckplatte begründet ist. Schließlich besteht auch die Möglichkeit, daß

alle drei Komponenten übereinstimmen und lediglich derjenige Anschlag, der ventral den Weg des Prothesenkerns in AP-Richtung begrenzt, unterschiedlich lokalisiert ist.

5 Wenn hier von unterer und oberer Deckplatte die Rede ist, so soll damit nicht Ausdruck gebracht werden, daß die den Sitz für den Kern bildende Deckplatte stets unten angebracht sein müßte. Vielmehr kann die Anordnung auch umgekehrt gewählt werden. In den Ansprüchen wird deshalb allgemeiner von einer
10 ersten und einer zweiten Deckplatte gesprochen.

Bevorzugte Ausführungsformen werden im folgenden anhand der Zeichnungen erläutert. Darin zeigen:

- 15 Fig. 1 einen Frontalschnitt
Fig. 2 einen Sagittalschnitt und
Fig. 3 eine Zerlegungsdarstellung einer ersten Ausführungsform;
Fig. 4 eine Variante der ersten Ausführungsform;
20 Fig. 5 einen Sagittalschnitt und
Fig. 6 eine Zerlegungsdarstellung einer zweiten Ausführungsform;
Fig. 7 die zweite Ausführungsform mit umgestellter Anschlagplatte;
25 Fig. 8 und 9 zwei Sagittalschnitte gem. den Schnittlinien B bzw. C in Fig. 10;
Fig. 10 und 11 zwei perspektivische Darstellungen der dritten Ausführungsform und
Fig. 12 die Anschlagplatte der dritten Ausführungsform;
30 Fig. 13 eine Zerlegungsdarstellung einer vierten Ausführungsform und

Fig. 14 eine Variante der unteren Deckplatte der vierten Ausführungsform.

Die untere Deckplatte 1 und die obere Deckplatte 2 der ersten
5 Ausführungsform weisen äußere Oberflächen 3 bzw. 4 auf, die zur Verankerung am zugehörigen Wirbelkörper bestimmt sind. Sie sind vorzugsweise eben. Es sind aber auch andere im wesentlichen flache Gestaltungen einschließlich geeigneter Oberflächenstrukturen zur besseren Verankerung am Knochen
10 denkbar. Die Deckplatten bestehen vorzugsweise aus Metall.

Die untere Deckplatte 1 wendet der oberen Deckplatte 2 eine ebene Bodenfläche 5 zu, die auf drei Seiten von einem Kragen 6 eingefast ist, der oberhalb eines inneren Hinterschnitts
15 eine nach innen ragende Leiste 7 bildet. Die untere Deckplatte 1 ist in der Draufsicht oval oder etwa rechteckig gestaltet.

Die Bodenfläche 5 und der Kragen 6 der unteren Deckplatte 1
20 bilden einen Sitz für den Prothesenkern 10, der aus gleitgünstigem Werkstoff, beispielsweise Polyethylen, besteht. Er hat eine zur Bodenfläche 5 passende ebene Unterfläche, die seitlich und dorsal von einer Randleiste 11 umgrenzt wird., oberhalb welcher sich eine Nut 12 befindet. Die Leiste 11 greift
25 in den Hinterschnitt des Kragens 6 unterhalb der Leiste 7. Die Leiste 7 greift in die Nut 12 ein. Dadurch ist der Prothesenkern 10 gegen Abheben von der unteren Deckplatte 1 gesichert. Zwischen dem Kragen 6 und der unteren Deckplatte 1 und dem Rand des Kerns 10 ist Gleitspiel vorhanden. Im Bereich ihrer Seiten 8, 9 verlaufen die dortigen Zweige des
30 Kragens 6 bzw. der Leisten 7 und 11 und der Nut 12 zueinander parallel und gradlinig.

Der Kern 10 hat allseits im wesentlichen dieselbe Umrißgestalt in der Draufsicht wie die untere Deckplatte 1 und die obere Deckplatte 2. Er überdeckt insbesondere den Kragen 6, so daß die Größe der von der Oberseite des Kerns zur Verfügung gestellten Gleitfläche 22 durch das Vorhandensein des Kragens 6 nicht verringert wird. Der Kragen 6 kann im Verhältnis zur Höhe des Kerns 10 klein ausgebildet sein. Trotzdem kann der Kern dem Zwischenraum zwischen den Deckplatten 1 und 2 nicht entweichen, weil er durch das Zusammenspiel der hinterschnittenen Leisten 7 und 11 am Abheben von der Deckplatte 1 gehindert wird.

An ihrem ventralen Rand weisen die Deckplatten 1, 2 je einen etwa rechtwinklig von ihnen abragenden Befestigungsflansch 15, 16 auf, der Schraubenlöcher 17 zur Befestigung am Wirbelkörper enthält. Im Flansch 15 der unteren Deckplatte 1 befindet sich ein Schlitz 18, der eine Gleitführung für eine Anschlagplatte 14 bildet, die darin verschiebbar gehalten ist. Sie kann die in Fig. 2 dargestellte Sperrstellung einnehmen, in welcher sie einen Anschlag für die nach vorne gerichtete Bewegung des Kerns 10 bildet. Sie kann in den Schlitz 18 auch soweit nach unten verschoben oder gänzlich daraus entfernt werden, daß der Prothesenkern leicht von ventral in den Sitz der unteren Deckplatte und zwischen die Deckplatten eingebracht werden kann. Sie enthält zwei Bohrungen 19, die in der Sperrstellung mit den Schraubenlöchern 17 fluchten. Wenn die untere Deckplatte 1 durch die Schraubenlöcher 17 hindurch am Wirbelkörper befestigt ist, gehen die Befestigungsschrauben auch durch die Löcher 19 und sichern dadurch die Anschlagplatte 14 in ihrer Sperrstellung.

Die seitlichen Zweige des Kragens 6 bilden mit ihrer Leiste 7 im Zusammenwirken mit der Leiste 11 und der Nut 12 des Kerns 10 eine Führungseinrichtung für den Prothesenkern 10, in welche dieser von der offenen ventralen Seite (in Fig. 2 rechts) her in AP-Richtung (in Fig. 3 angedeutet) eingeschoben werden kann. Der dorsale Teil 21 des Kragens 6 wirkt als Sicherungsanschlag, der ein Entweichen des Kerns in dorsaler Richtung aus dem Zwischenraum zwischen den Deckplatten 1 und 2 verhindert. Auf das Vorhandensein des Hinterschnitts an dem Kragen 6 und am Rand des Kerns 10 kommt es für die Führungsfunktion nur in den seitlichen Bereichen 8 und 9 der unteren Deckplatte 1 und des Kerns 10 an, nicht aber im dorsalen Verlauf 21 des Kragens 6.

Oberseitig weist der Kern 10 eine vorzugsweise konvex-sphärische Gelenkfläche 22 auf, die zur Bildung eines Gelenks zusammenwirkt mit der unterseitigen, konkav-sphärischen Gleitfläche 23 der oberen Deckplatte 2.

Während der Prothesenkern 10 in der Ausführungsform gemäß Fig. 2 in montiertem Zustand unbeweglich festgelegt ist zwischen dem dorsalen Anschlag 21 und dem ventralen Anschlag 14, zeigt Fig. 4 eine Variante, in welcher der Prothesenkern 10 ventral (in Fig. 4 rechts) ein wenig kürzer ist als die untere Deckplatte, so daß zwischen ihrer ventralen Endfläche 13 und dem Anschlag 14 Spiel verbleibt, wenn sich der Prothesenkern in seiner weitest dorsalen Stellung befindet. Um die Größe dieses Spiels kann sich der Kern 10 im montierten Zustand in der AP-Richtung. Bei der Beugebewegung schwenkt die obere Deckplatte 2 im Verhältnis zur unteren Deckplatte 1 in der Ansicht gemäß Fig. 4 ein wenig im Uhrzeigersinn und bei

der Streckbewegung entgegengesetzt. Wenn die obere Deckplatte 2 dabei genau der durch die Gleitflächen 22, 23 vorgegebenen Richtung folgt, ist diese Schwenkbewegung mit einer translatorischen Bewegung verknüpft, die bei der Beugung nach vorne (in Fig. 4 nach rechts) und bei der Streckung nach hinten (in Fig. 4 nach links) gerichtet ist. Ein Teil dieser translatorischen Bewegung kann den physiologischen Gegebenheiten widersprechen und zu unerwünschten Spannungen führen. Diese Spannungen verursachen rückstellende Kräfte, die bei der erfindungsgemäßen Prothesengestaltung dazu führen, daß die obere Deckplatte sich relativ zur unteren Deckplatte entgegengesetzt bewegt und dadurch die unerwünschte Bewegungskomponente kompensiert.

Zwischen den zusammenwirkenden Führungseinrichtungen des Kerns und der Deckplatte kann in seitlicher Richtung so viel Spiel gelassen werden, daß auch in dieser Richtung eine gewisse Relativbewegung möglich ist.

Das Ausmaß des Bewegungsspiels in AP-Richtung liegt bei einer Zervikalprothese vorzugsweise zwischen ein und vier, weiter vorzugsweise in der Größenordnung von zwei bis drei Millimetern. Falls eine Relativbeweglichkeit in seitlicher Richtung vorgesehen ist, sollte deren Ausmaß nicht über zwei Millimeter hinausgehen.

Für das zweite Ausführungsbeispiel gilt die obige Beschreibung mit Ausnahme des ventralen Anschlags. An ihrem ventralen Rand weisen die Deckplatten 1, 2 je einen rechtwinklig von ihnen abragenden Flansch 15, 16 auf, der Schraubenlöcher 17 zur Befestigung am Wirbelkörper enthält. Am Flansch 15 der unteren Deckplatte 1 ist mittig zwischen zwei Schraubenlö-

chern 17 eine Anschlagplatte 28 mittels eines Kopfbolzens 29 drehbar befestigt. Die Ebene, in der sie sich gleitend drehen kann, wird durch die Frontfläche des Befestigungsflanschs 15 bestimmt, die deshalb als Gleitführungsfläche bezeichnet wird. Die Anschlagplatte weist zwei sich im wesentlichen zur Seite hin erstreckende Flügel 30 und eine sich quer dazu erstreckende Zunge 31 auf. Sie besteht aus federndem Metall und ist so vorgespannt, daß ihre Flügel 30 gegen die Gleitführungsfläche drücken. Zum Eingriff eines Drehwerkzeugs, beispielsweise eines Schraubenziehers, enthält sie eine passende Öffnung oder Vertiefung 32. Wenn sie sich in der in Fig. 6 dargestellten Montagestellung befindet, ragt sie nicht über die Bodenfläche 5 der unteren Deckplatte hinaus. Der Kern 10 kann daher unbehindert in die von dem Kragen 6 gebildete Einschubführung eingeschoben werden. Wird sie um 180° gedreht, wie es in Fig. 5 und 7 dargestellt ist, ragt die Zunge 31 über die Oberfläche 5 und bildet dadurch einen Anschlag, der den Kern 10 am Verlassen der Führung zur ventralen Seite hin hindert.

In der in Fig. 6 gezeigten Montagestellung läßt die Anschlagplatte 28 die Schraubenlöcher 17 für die Montage der Befestigungsschrauben frei. Wie in Fig. 7 gezeigt, überdecken die Flügel 30 in der Sicherungsstellung ganz oder teilweise die Schraubenlöcher 17 und drücken elastisch auf die darin befindlichen Schraubenköpfe, um sie am Heraustreten aus den Schraubenlöchern 17 zu hindern. Sie enthalten eine Öffnung, die sich unter der Vorspannung einrastend über die Kuppen der in Fig 7 angedeuteten Schraubenköpfe 33 legt und dadurch die Sicherungsplatte am Verlassen der Sicherungsstellung hindert.

Zwischen der als Anschlag für den Prothesenkern 10 vorgesehenen Zunge 31 der Anschlagplatte 28 und der ihr gegenüberstehenden Fläche 13 des Kerns 10 kann sich - wie in Fig. 7 angedeutet - ein Freiraum von wenigen Millimetern befinden. Dadurch kann sich der Kern 10 in der von den seitlichen Abschnitten 8, 9 des Kragens 6 gebildeten Führung um eine gewisse Strecke in AP-Richtung bewegen (siehe die Beschreibung zu Fig. 4). Wenn dieses Bewegungsspiel nicht gewünscht wird, reduziert man den Freiraum zwischen der Fläche 13 und dem Anschlag 14 auf Null, wie es in Fig. 6 vorausgesetzt ist.

Für die dritte Ausführungsform gemäß Fig. 8 bis 12 gilt die obige Beschreibung zu Fig. 1 bis 3 mit Ausnahme der ventralen Anschlagvorrichtung.

Entlang dem ventralen Rand der unteren Deckplatte 1 ist ein Schlitz 40 eingeschnitten, der in der in Fig. 10 linken Hälfte des Flanschs 15 vollständig von oben bis unten durchgeht und im rechten Teil des Flanschs 15 von der in Fig. 10 gestrichelt dargestellten Linie 41 begrenzt ist. Dem Schlitz 40 gegenüber ist in die Unterseite des Prothesenkerns 10 ein mit dem Schlitz 40 fluchtender Schlitz 42 eingeschnitten. Die beiden Schlitz 40, 42 dienen zur Aufnahme einer Anschlagplatte 43 deren Umriß etwa den Begrenzungen des zu seiner Aufnahme bestimmten Raums gleicht, der durch die Schlitz 40, 42 gebildet ist. Wie Fig. 10 zeigt, kann sie nach dem Einsetzen des Prothesenkerns 10 von der Seite her in die Schlitz 40, 42 eingeschoben werden.

Die Anschlagplatte 43 kann am Ende mit einer Nase 44 versehen sein, die nach dem vollständigen Einschieben der Anschlagplatte 43 in die Schlitz 40, 42 auf der rechten Seite (siehe

Fig. 11) herauszuschauen und zur Sicherung der Anschlagplatte umgebogen werden kann. Der Flansch 15 weist Schraubenlöcher 17 auf, die zur Befestigung der unteren Deckplatte 1 am zugehörigen Wirbelkörper dienen. Im linken Teil (siehe Fig. 10) durchquert das dortige Schraubenloch 17 den Schlitz 40, der sich dort über die gesamte Höhe des Flanschs 15 erstreckt, um den linken, breiten Flügel 45 der Anschlagplatte aufzunehmen. Dieser breite Flügel 45 der Anschlagplatte enthält ebenfalls ein Schraubenloch 46, daß dann, wenn die Anschlagplatte 43 eingeschoben ist (Fig. 9 und 11) mit dem dortigen Schraubenloch 17 fluchtet. Wenn sich in diesem Schraubenloch eine Befestigungsschraube befindet, kann die Anschlagplatte 43 nicht aus ihrer Sicherungsstellung entweichen.

Das Schraubenloch 46 und die Nase 44 bilden voneinander unabhängig wirkende Sicherungseinrichtungen. Es ist deshalb nicht erforderlich, daß stets alle beide vorgesehen sind. Wenn das Schraubenloch 46 vorhanden ist, kann die Nase 44 fehlen. Wenn die Nase vorgesehen ist, können der breite Flügel 45 der Anschlagplatte unterhalb der Linie 47 sowie der entsprechende Teil des Schlitzes im Befestigungsflansch 15 fehlen. Es genügt dann eine Anschlagplatte, die oberhalb der strichpunktierten Linie 47 (Fig. 12) verläuft. Damit die Anschlagplatte in diesem Falle auch nicht nach rechts aus dem Aufnahmeschlitz 40, 42 entweichen kann, kann eine der Nase 44 entsprechende Sicherungsnase (nicht gezeigt) auch am linken Ende der Anschlagplatte 43 vorgesehen sein. Nach oben kann die Anschlagplatte 43 nicht entweichen, weil sie überdeckt wird von demjenigen Teil des Prothesenkerns 10, der den Schlitz 42 bildet.

Die vierte Ausführungsform gemäß Fig. 13 und 14 veranschaulicht eine alternative Ausführungsmöglichkeit für den Sitz, der an der unteren Deckplatte 1 für den Prothesenkern 10 gebildet ist. In dieser Ausführungsform besteht die Prothese aus einer unteren Deckplatte 51 und einer oberen Deckplatte 52. Die untere Deckplatte weist eine obere, ebene Bodenfläche 53 auf, auf der der Prothesenkern 54 aufliegt. Während dieser Kern in den zuvor erläuterten Ausführungsformen an seinen Außenrändern geführt ist, besitzt er in der vierten Ausführungsform eine Ausnehmung 55 mit hinterschnittenen Innenrändern 56, die mit einem langgestreckten Vorsprung 57 der unteren Deckplatte mit entsprechend hinterschnittenen Rändern 58 zusammenwirken. Der Kern 54 wird dadurch - ebenso wie unter Bezugnahme auf das erste Ausführungsbeispiel erläutert - in AP-Richtung beweglich gegenüber der unteren Deckplatte 51 geführt. Außerdem ist er durch die zusammenwirkenden Hinterschnitte gegen ein Anheben von der unteren Deckplatte geschützt. Es sind nicht gezeigte Anschläge vorgesehen, die das dorsale und ventrale Herausrutschen des Prothesenkerns aus dem Plattenzwischenraum verhindern.

Die untere Deckplatte 51 kann durch die in Fig. 14 dargestellte untere Deckplatte 51a ersetzt werden, die sich von der unteren Deckplatte 31 dadurch unterscheidet, daß ihr Vorsprung 57a nicht langgestreckt, sondern in der Draufsicht kreisförmig begrenzt ausgeführt ist. Dies ermöglicht dem Prothesenkern 54, von dem angenommen wird, daß er in bezug auf eine vertikale Achse mit der oberen Deckplatte 52 drehverbunden ist, eine Rotation um den Vorsprung 57a, ohne die gewünschte AP-Bewegung zu behindern. Dies kann bei asphärischer Ausbildung der Gleitflächen zwischen Kern 54 und oberer Deckplatte 52 erwünscht sein.

Patentansprüche

1. Zwischenwirbelprothese, insbesondere für die Halswirbel-
5 säule, die im wesentliche aus einer ersten, mit einem ersten Wirbelkörper zu verbindenden Deckplatte (1, 51), einer zweiten, mit dem zweiten Wirbelkörper zu verbindenden Deckplatte (2, 52) und einem Prothesenkern (10, 54) besteht, der mit der zweiten Deckplatte (2, 52) ein Gelenk
10 bildet und von einem Sitz der ersten Deckplatte (1, 51) gehalten ist, der als Führungseinrichtung (7, 11, 12, 56, 57, 57a) ausgebildet ist, in die der Kern (10, 54) relativ zur ersten Deckplatte (1, 51) von der ventralen Seite her hineinbewegbar ist, dadurch gekennzeichnet, daß
15 die erste Deckplatte (1, 51) an ihrem ventralen Rand eine Gleitführung (18, 29, 40) aufweist, in oder an welcher ein Anschlag (14, 31, 43) zwischen einer sperrenden Stellung und einer nicht sperrenden Stellung verschiebbar ist.
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2. Prothese nach Anspruch 1 dadurch gekennzeichnet, daß eine Einrichtung (19, 33, 46, 44) zum Fixieren des Anschlags in der sperrenden Stellung vorgesehen ist.
- 25 3. Prothese nach Anspruch 1 oder 2 dadurch gekennzeichnet, daß die Gleitführung von einem quer zur Führungseinrichtung (7, 11, 12, 56, 57, 57a) verlaufenden Führungsschlitz (18) gebildet ist, der den als Anschlagplatte (14) ausgebildeten Anschlag aufnimmt.
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4. Prothese nach Anspruch 3 dadurch gekennzeichnet, daß der Führungsschlitz (18) eine quer zur Erstreckungsebene der

ersten Deckplatte (1) verlaufende Führungsrichtung (D) hat und die in dieser Führungsrichtung (D) bewegbare Anschlagplatte (14) in ihrer sperrenden Stellung teilweise in dem Schlitz (18) gehalten ist und teilweise über die Bodenfläche (5) der ersten Deckplatte hinausragt.

- 5
5. Prothese nach Anspruch 4 dadurch gekennzeichnet, daß der Führungsschlitz (18) von wenigstens einem Schraubenloch (17) durchquert ist und die Anschlagplatte (14) ein in
- 10 ihrer sperrenden Stellung damit fluchtendes Schraubenloch (19) aufweist.
6. Prothese nach Anspruch 4 dadurch gekennzeichnet, daß der Führungsschlitz (18) im ventralen Rand der ersten Deck-
- 15 platte und einem daran angeordneten Befestigungsflansch (15) vorgesehen ist.
7. Prothese nach Anspruch 3 dadurch gekennzeichnet, daß der Führungsschlitz (40) eine parallel zur Erstreckungsebene
- 20 der ersten Deckplatte (1) und quer zur AP-Richtung verlaufende Führungsrichtung (E) hat und die Anschlagplatte (43) in dieser Richtung in die sperrende Stellung bewegbar ist.
- 25 8. Prothese nach Anspruch 7 dadurch gekennzeichnet, daß der Prothesenkern (10) einen die im Führungsschlitz (40) enthaltende Anschlagplatte (43) überdeckenden Teil aufweist, der die Anschlagplatte (43) daran hindert, den Führungsschlitz (40) quer zu dessen Führungsrichtung (E) zu ver-
- 30 lassen.

9. Prothese nach Anspruch 4 oder 8 dadurch gekennzeichnet, daß der Prothesenkern einen mit dem Führungsschlitz (49) fluchtenden, einen Teil der Anschlagplatte (43) aufnehmenden Schlitz (42) aufweist.

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10. Prothese nach Anspruch 7 dadurch gekennzeichnet, daß der Führungsschlitz (40) von wenigstens einem Schraubenloch (17) durchquert ist und die Anschlagplatte (43) ein in ihrer sperrenden Stellung damit fluchtendes Schraubenloch (46) aufweist.

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11. Prothese nach einem der Ansprüche 3 bis 10 dadurch gekennzeichnet, daß die Anschlagplatte (14, 43) eine in der Führungsrichtung (D,E) des Führungsschlitzes (18, 40) hinausragende, leicht biegbare Sicherungsnase (44) aufweist.

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12. Prothese nach Anspruch 1 oder 2 dadurch gekennzeichnet, daß die Gleitführung für eine Anschlagplatte (28) von einer am ventralen Rand der ersten Deckplatte (1) quer zur AP-Richtung (A) verlaufenden Gleitführungsfläche und einem sich davon erhebenden Schwenkbolzen (29) gebildet ist, auf dem die Anschlagplatte (28) schwenkbar gelagert ist, und daß die Anschlagplatte (28) eine Zunge (31) aufweist, die in einer sperrenden Schwenkstellung der Anschlagplatte (28) über die Bodenfläche (5) der ersten Deckplatte hinausragt und in der nicht sperrenden Stellung unter die Bodenfläche (5) der ersten Deckplatte abgesenkt ist.

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13. Prothese nach Anspruch 12 dadurch gekennzeichnet, daß in der Nachbarschaft des Schwenkbolzens (30) mindestens ein

Schraubenloch (17) vorgesehen ist und die Anschlagplatte (30) in der sperrenden Stellung mit einem Flügel (30) über einen in dem Schraubenloch (17) befindlichen Schraubenkopf faßt.

5

14. Prothese nach einem der Ansprüche 1 bis 13 dadurch gekennzeichnet, daß die Gelenkfläche (22) des Prothesenkerns (10) im wesentlichen die gesamte erste Deckplatte (1) überdeckt.

10

15. Prothese nach Anspruch 14 dadurch gekennzeichnet, daß der Prothesenkern (10) relativ zur ersten Deckplatte (1) auch dann in AP-Richtung beweglich ist, wenn sich der Anschlag in der sperrenden Stellung befindet.

15

GEÄNDERTE ANSPRÜCHE

[beim Internationalen Büro am 17 März 2003 (17.03.03) eingegangen,
Ansprüche 16 – 19 hinzugefügt]

Schraubenloch (17) vorgesehen ist und die Anschlagplatte (30) in der sperrenden Stellung mit einem Flügel (30) über einen in dem Schraubenloch (17) befindlichen Schraubenkopf faßt.

5

14. Prothese nach einem der Ansprüche 1 bis 13 dadurch gekennzeichnet, daß die Gelenkfläche (22) des Prothesenkerns (10) im wesentlichen die gesamte erste Deckplatte (1) überdeckt.

10

15. Prothese nach Anspruch 14 dadurch gekennzeichnet, daß der Prothesenkern (10) relativ zur ersten Deckplatte (1) auch dann in AP-Richtung beweglich ist, wenn sich der Anschlag in der sperrenden Stellung befindet.

15

16. System von Zwischenwirbelprothesen, insbesondere für die Halswirbelsäule, die im wesentlichen aus einer ersten, mit einem ersten Wirbelkörper zu verbindenden Deckplatte, einem zweiten, mit dem zweiten Wirbelkörper zu verbindenden Deckplatte und einem Prothesenkern bestehen, der von einem Sitz der ersten Deckplatte gehalten ist und mit der zweiten Deckplatte ein Gelenk bildet, dadurch gekennzeichnet, daß das System neben Zwischenwirbelprothesentypen nach einem der Ansprüche 1 bis 15 solche Typen mit übereinstimmender Außenform umfaßt, die keine AP-Beweglichkeit zwischen dem Prothesenkern und der ersten Deckplatte aufweisen.

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17. System nach Anspruch 16, dadurch gekennzeichnet, daß die Deckplatten der einander entsprechenden Typen mit bzw. ohne AP-Beweglichkeit übereinstimmen und der Kern unter-

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schiedlich ist.

- 5 18. System nach Anspruch 16, dadurch gekennzeichnet, daß die zweite Deckplatte und der Prothesenkern der einander entsprechenden Typen mit bzw. ohne AP-Beweglichkeit übereinstimmen und die erste Deckplatte unterschiedlich ist.
- 10 19. System nach Anspruch 16, dadurch gekennzeichnet, daß alle drei Komponenten übereinstimmen und ein Anschlag, der die Beweglichkeit des Prothesenkerns ventral begrenzt, unterschiedlich ist.

1 / 5

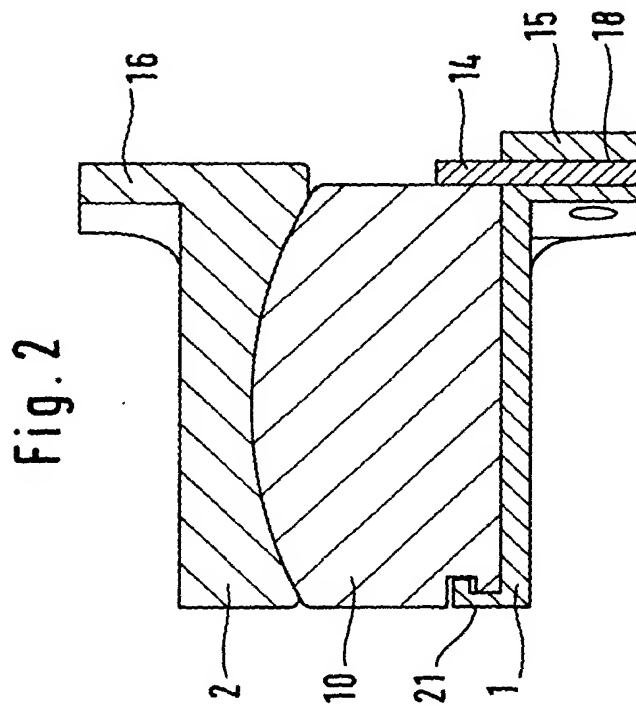
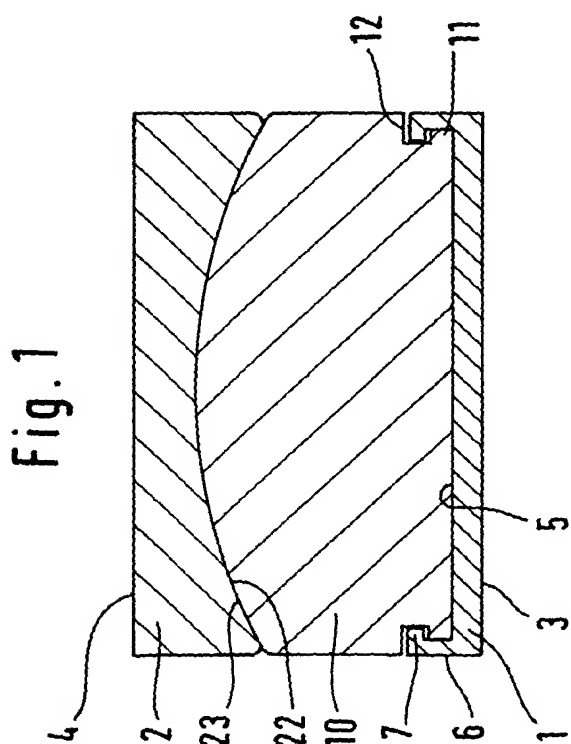
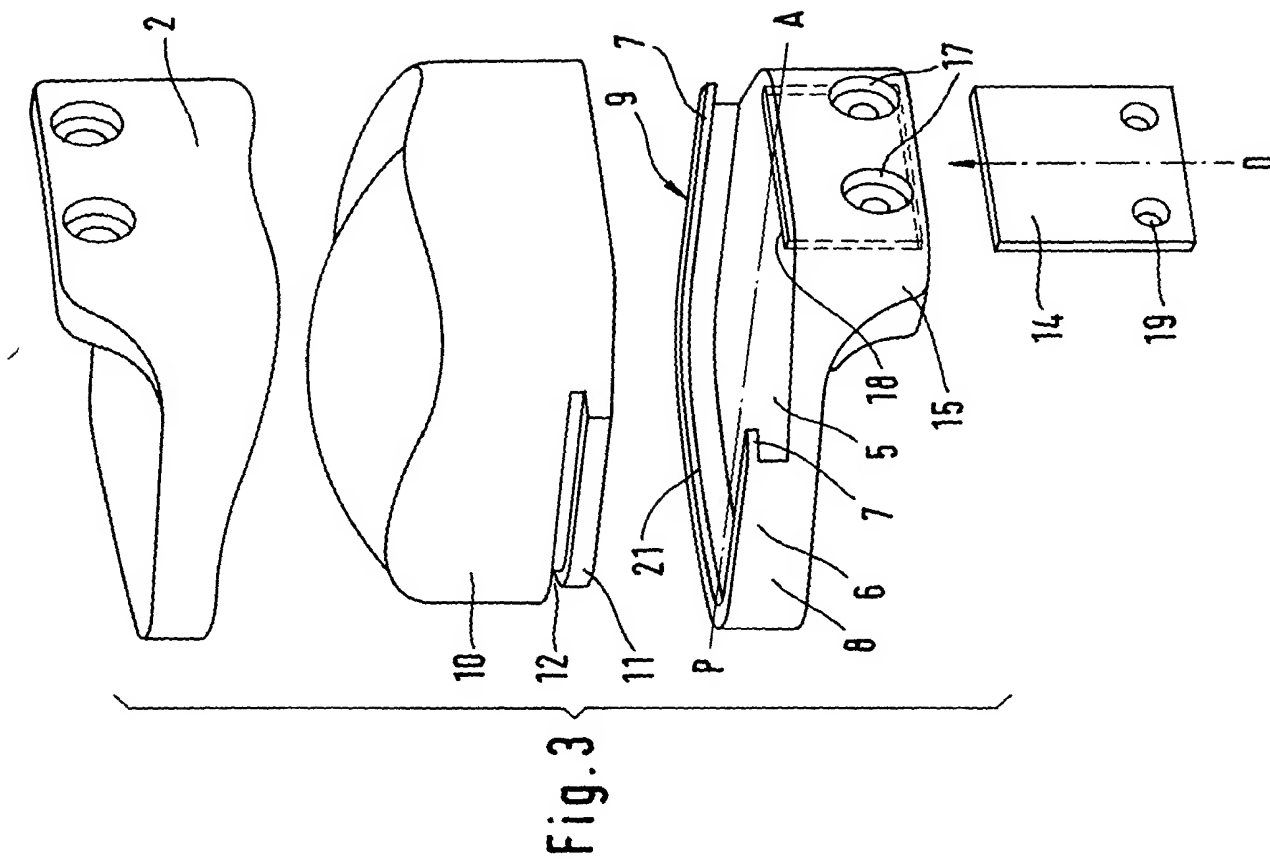


Fig. 4

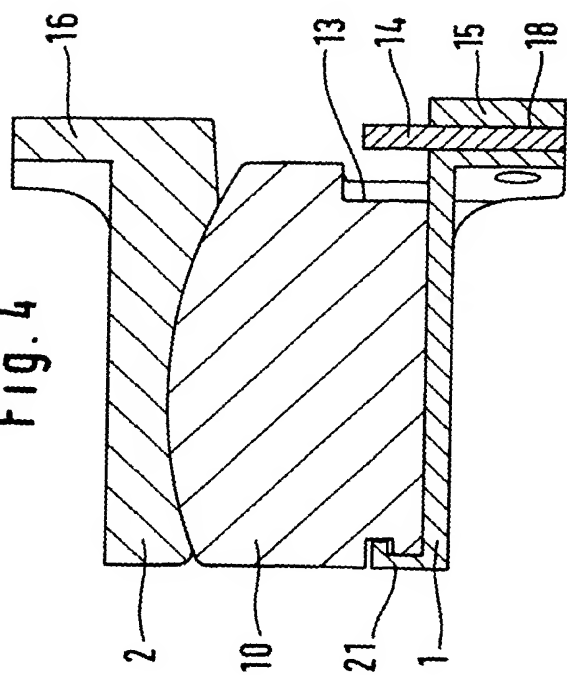


Fig. 5

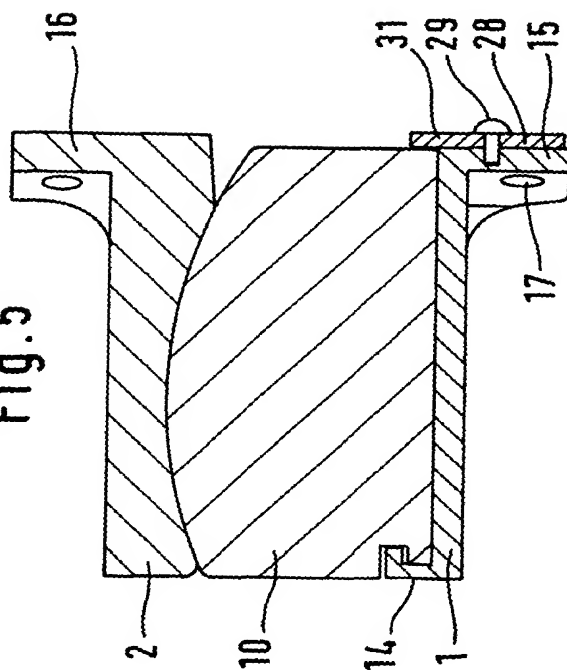


Fig. 8

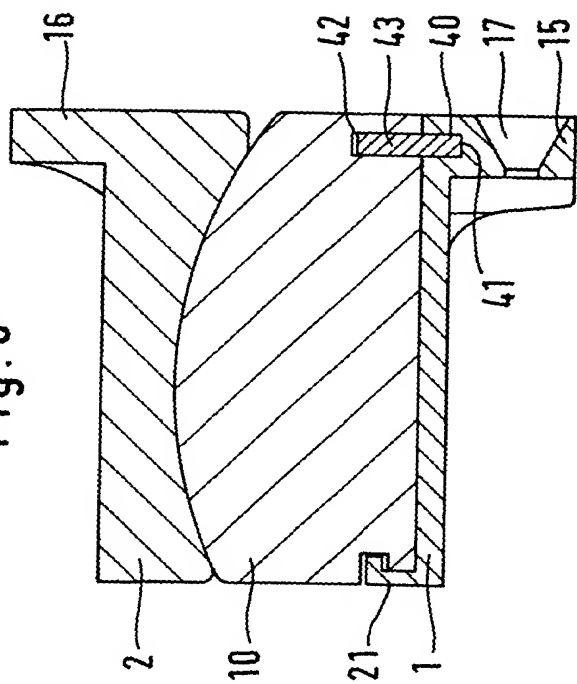
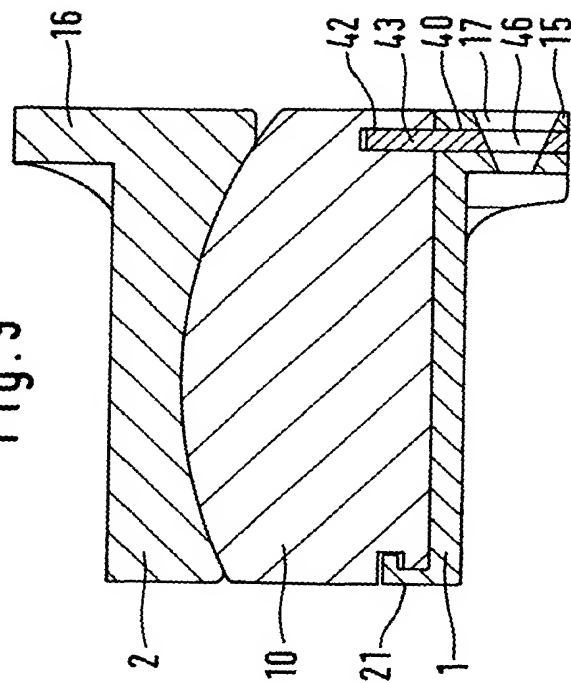


Fig. 9



3 / 5

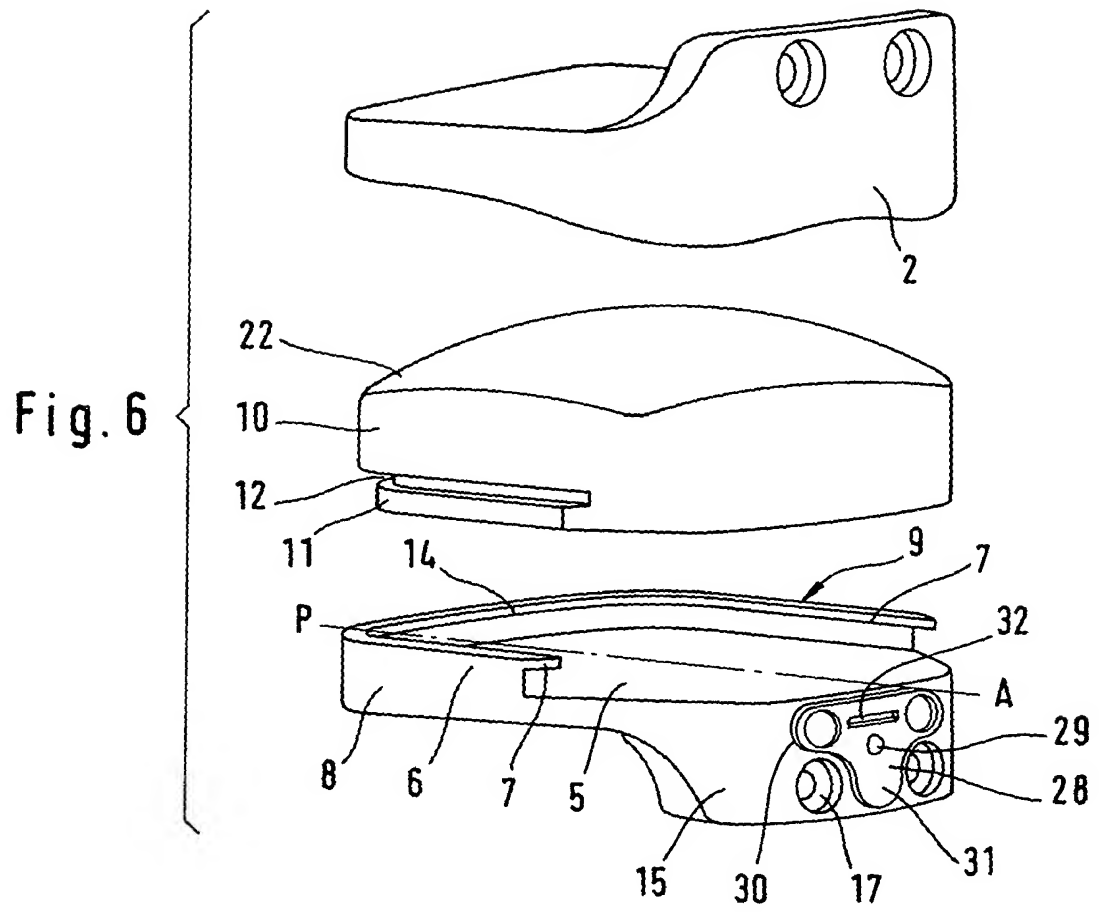
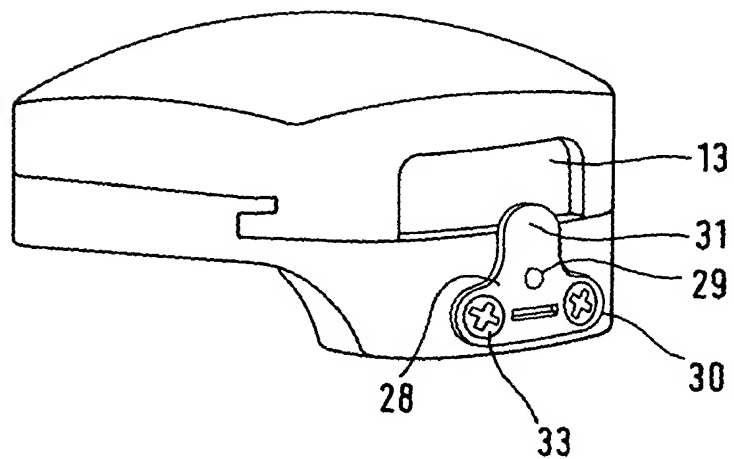


Fig. 7



4 / 5

Fig. 10

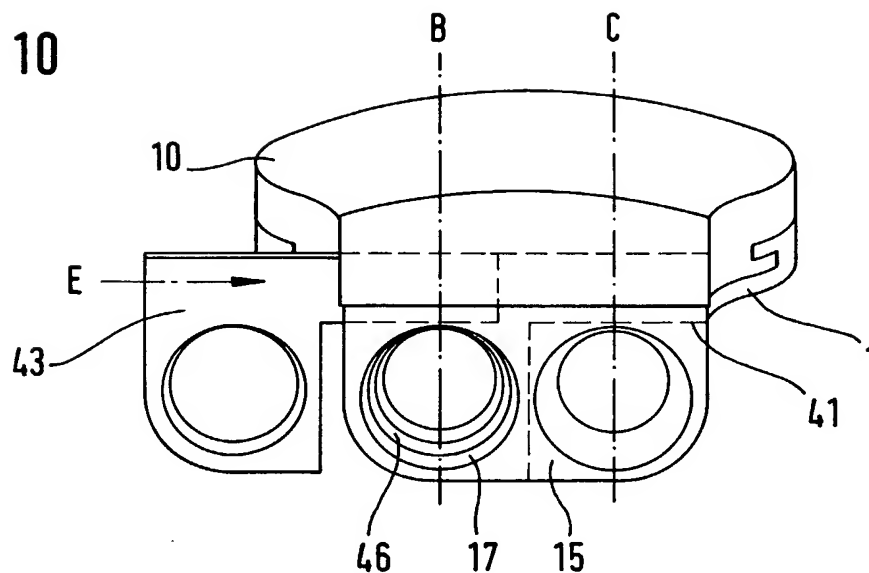


Fig. 11

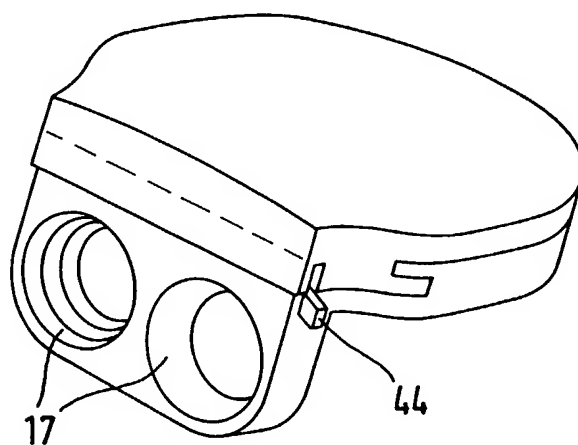
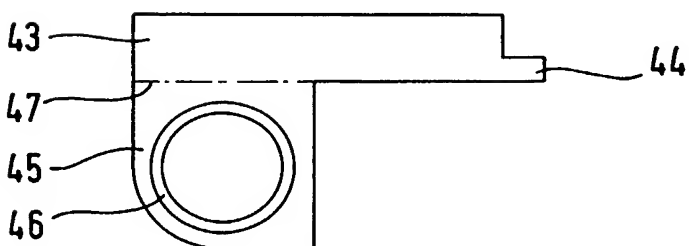
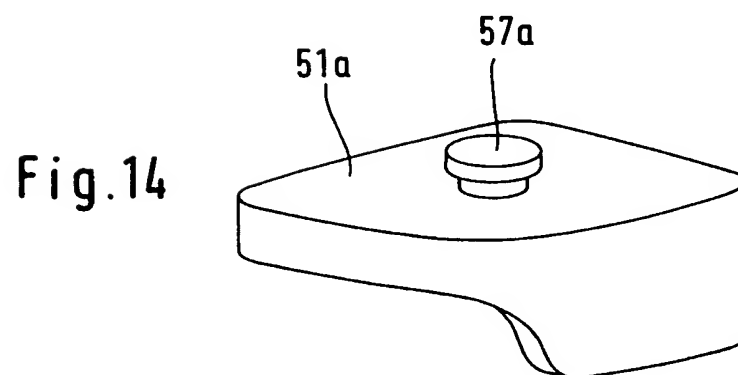
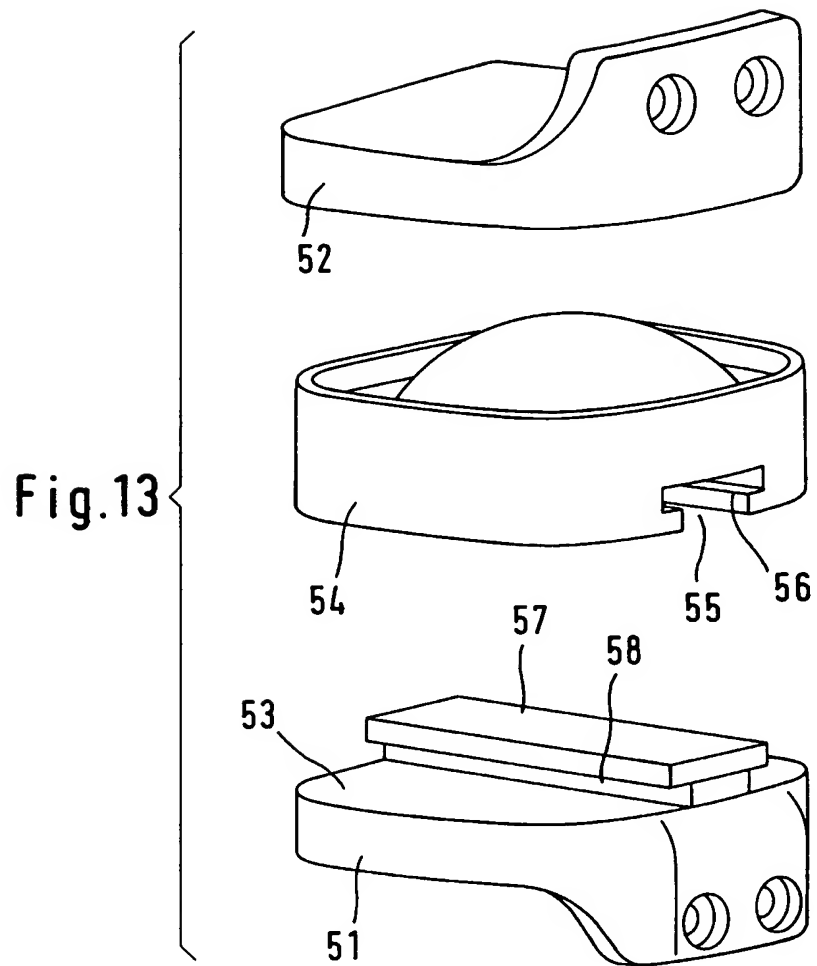


Fig. 12



5 / 5



INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 02/11524

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2 718 635 A (AXCYL MEDICAL) 20 October 1995 (1995-10-20) claims 1-5; figures 4-7,9,11 ---	1,2
Y	WO 99 65412 A (PIONEER LAB INC ;UNIV MICHIGAN TECH (US)) 23 December 1999 (1999-12-23) figures page 6, line 4 -page 8, line 10 ---	1,2
A	---	3-6
A	US 5 425 773 A (PETTINE KENNETH A ET AL) 20 June 1995 (1995-06-20) figures 5-21 column 6, line 27 - line 45 column 9, line 7 - line 20 ---	1,2
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Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 02/11524

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01 01893 A (BEYERSDORFF BORIS ;MARNAY THIERRY (FR); SPINE SOLUTIONS INC (US)) 11 January 2001 (2001-01-11) figures ----	1
A	EP 0 978 258 A (HOWMEDICA GMBH) 9 February 2000 (2000-02-09) -----	

INTERNATIONAL SEARCH REPORT

Information on patent family members

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			US 2002169508 A1	14-11-2002
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A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES

IPK 7 A61F2/44

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)

IPK 7 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	FR 2 718 635 A (AXCYL MEDICAL) 20. Oktober 1995 (1995-10-20) Ansprüche 1-5; Abbildungen 4-7,9,11 ---	1,2
Y	WO 99 65412 A (PIONEER LAB INC ;UNIV MICHIGAN TECH (US)) 23. Dezember 1999 (1999-12-23) Abbildungen Seite 6, Zeile 4 -Seite 8, Zeile 10 ---	1,2
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A	US 5 425 773 A (PETTINE KENNETH A ET AL) 20. Juni 1995 (1995-06-20) Abbildungen 5-21 Spalte 6, Zeile 27 - Zeile 45 Spalte 9, Zeile 7 - Zeile 20 --- -/--	1,2



Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen



Siehe Anhang Patentfamilie

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C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
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INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen

PCT/EP 02/11524

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			EP	0978258 A1	09-02-2000
			JP	2000152943 A	06-06-2000
			US	6296647 B1	02-10-2001

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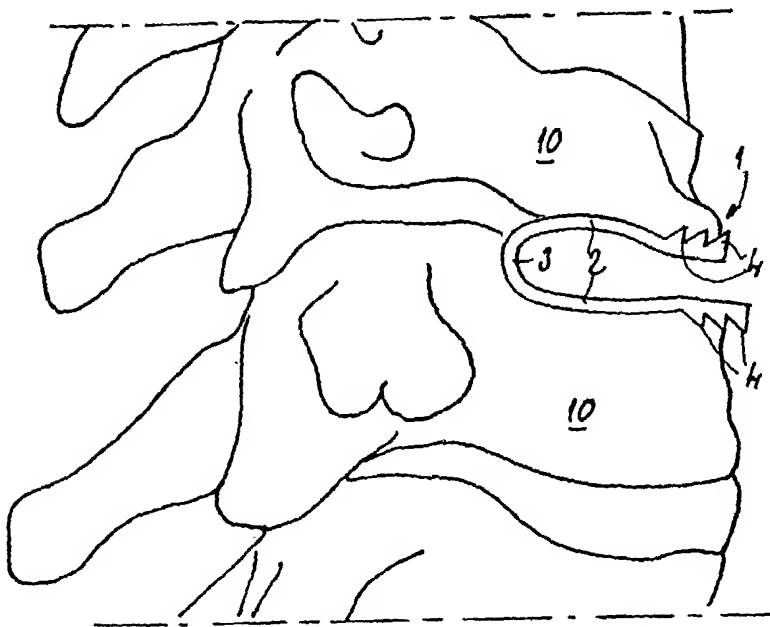
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[Suite sur la page suivante]

(54) Title: DYNAMIC INTERVERTEBRAL IMPLANT

(54) Titre : IMPLANT INTERVERTEBRAL DYNAMIQUE



(57) **Abstract:** The implant (1) comprises two side walls (2) resting against the vertebral end-plates and an intermediate wall (3) joining said supporting walls. The implant (1) can be deformed for insertion between the vertebrae (10) to be treated and in order to restore the attenuated mobility of said vertebrae (10), and comprises means (4) for the mounting thereof on said vertebrae (10). According to the invention, said side walls (2), when seen from the side, have a curved shape, whereby the convexity thereof is oriented towards the outside of the implant (1); said intermediate wall (3) has a curved shape, whereby the convexity thereof is oriented towards the outside of the implant (1) and is such that it does not form any pronounced angles with the supporting side walls (2). The supporting side walls (2) and the intermediate wall (3), when seen from the side, have a partially oval shape like a water droplet; and the means (4) for fixing the implant (1) to the vertebrae (10) are configured in such a way that said implant (1) can be mounted on the vertebrae (10), i.e. the implant (1) can be

slightly deformed in relation to the vertebrae (10) during the movement of said vertebrae.

(57) **Abrégé :** Cet implant (1) comprend deux parois latérales (2) d'appui contre les plateaux vertébraux et une paroi intermédiaire (3) de raccordement de ces parois latérales d'appui, cet implant (1) étant déformable élastiquement pour son insertion entre les vertèbres (10) à traiter et pour permettre de restaurer une mobilité amortie de ces vertèbres (10), et comprenant des moyens (4) pour son assemblage à ces vertèbres (10). Selon l'invention, - lesdites parois latérales (2) présentent vues de profil, des formes courbes avec leur convexité tournée vers l'extérieur de l'implant (1); - ladite paroi intermédiaire (3) présente une forme courbe, avec sa convexité tournée vers l'extérieur de l'implant (1), et est telle

[Suite sur la page suivante]

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TR), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

qu'elle ne forme pas d'angles marqués avec lesdites parois latérales d'appui (2), ces parois latérales d'appui (2) et cette paroi intermédiaire (3) ayant ainsi, vues de profil, une forme partiellement ovale, "en goutte d'eau" ; et- les moyens (4) de fixation de l'implant (1) aux vertèbres (10) sont conçus pour permettre un assemblage non rigide de cet implant (1) à ces vertèbres (10), c'est-à-dire autorisant une légère déformation de l'implant (1) par rapport aux vertèbres (10) lors du mouvement de ces vertèbres.

IMPLANT INTERVERTEBRAL DYNAMIQUE

La présente invention concerne un implant intervertébral, notamment destiné au traitement de vertèbres cervicales par voie d'abord antérieur.

5 Il est connu d'utiliser des implants intervertébraux pour restaurer l'espace intervertébral anatomique entre deux vertèbres. Toutefois, les implants existants ne donnent pas parfaitement satisfaction, particulièrement en ce qui concerne le traitement de vertèbres cervicales par voie d'abord antérieur, soit qu'ils ne restaurent pas parfaitement l'espace intervertébral, soit
10 qu'ils forment des obstacles aux mouvements des vertèbres, soit qu'ils induisent des risques d'insertion dans les plateaux vertébraux, soit qu'ils sont difficiles à implanter, soit que leur pérennité ou celle de leur ancrage est sujette à caution.

Le document US 5 749 916 décrit une cage de fusion fendue
15 latéralement, pour permettre l'exercice de contraintes sur un greffon contenu dans la cale et/ou la restauration de la mobilité anatomique entre deux vertèbres.

Cet implant n'est pas destiné au traitement de vertèbres cervicales par voie d'abord antérieur, et l'implant selon l'invention ne comprend pas une
20 telle fente latérale.

Il est par ailleurs connu, par le document WO 01/62190, un implant intervertébral comprenant un corps en forme de U vu de profil, c'est-à-dire présentant deux branches latérales d'appui contre les plateaux verticaux et un "mur" postérieur. Ce corps est déformable élastiquement pour son insertion
25 entre les vertèbres à traiter et pour permettre de restaurer la mobilité des vertèbres, et forme des pattes saillantes pour sa fixation aux vertèbres.

Cet implant est estimé comme ne donnant pas satisfaction du point de vue de la restauration d'un espace intervertébral avec mobilité des vertèbres. En effet, la fixation par vis de cet implant est considérée comme non
30 adaptée à une telle restauration, compte tenu des risques qu'elle induit d'une fusion vertébrale par croissance des cellules osseuses, de laquelle il peut résulter une immobilisation des vertèbres. De plus, la résistance de cet implant aux sollicitations répétées transmises par ces vertèbres est considérée comme sujette à caution.

35 La présente invention vise à remédier à ces inconvénients.

Son objectif principal est donc de fournir un implant intervertébral à même de restaurer un espace anatomique adéquat entre deux vertèbres tout en conservant, de manière certaine dans le temps, la mobilité relative des deux vertèbres traitées.

5 Un autre objectif de l'invention est de fournir un implant intervertébral ayant une parfaite résistance aux sollicitations répétées transmises par ces vertèbres.

10 L'implant concerné comprend, comme cela est connu, deux parois latérales d'appui contre les plateaux vertébraux et une paroi intermédiaire de raccordement de ces parois latérales d'appui, cet implant étant déformable élastiquement pour son insertion entre les vertèbres à traiter et pour permettre de restaurer une mobilité amortie de ces vertèbres, et comprenant des moyens pour son assemblage à ces vertèbres.

Selon l'invention,

15 - lesdites parois latérales d'appui présentent, vues de profil, des formes courbes avec leur convexité tournée vers l'extérieur de l'implant ;

20 - ladite paroi intermédiaire présente une forme courbe, avec sa convexité tournée vers l'extérieur de l'implant, et est telle qu'elle ne forme pas d'angles marqués avec lesdites parois latérales d'appui, ces parois latérales d'appui et cette paroi intermédiaire ayant ainsi, vues de profil, une forme partiellement ovale, "en goutte d'eau" ; et

25 - les moyens de fixation de l'implant aux vertèbres sont conçus pour permettre un assemblage non rigide de cet implant à ces vertèbres, c'est-à-dire autorisant une légère déformation de l'implant par rapport aux vertèbres lors du mouvement de ces vertèbres.

La forme courbe desdites parois latérales permet à ces parois de s'adapter précisément à la forme que présentent les faces respectives des plateaux vertébraux, assurant ainsi une certaine rétention de l'implant entre les vertèbres.

30 Une fois mis en place, l'implant ne fait pas obstacle aux mouvements des vertèbres compte tenu de la déformabilité de sa paroi intermédiaire ; le risque d'insertion de l'implant dans les plateaux vertébraux est dès lors fortement réduit, voire éliminé, d'autant plus que lesdites parois latérales présentent de larges surfaces de contact avec les plateaux
35 vertébraux.

L'absence d'angles marqués entre lesdites parois latérales d'appui et ladite paroi intermédiaire permet d'éviter, sur le corps de l'implant, toute concentration des contraintes transmises par les vertèbres en un emplacement localisé de ce corps, et permet par conséquent à cet implant d'avoir une parfaite résistance à ces contraintes au cours du temps.

La forme précitée du corps de l'implant permet par ailleurs une certaine déformation de l'implant par rapport aux vertèbres lors des mouvements de ces dernières, non empêchée par lesdits moyens de fixation de cet implant aux vertèbres et seulement limitée par ceux-ci.

Cette mobilité prévient tout risque de fusion de l'espace intervertébral par suite d'une croissance des cellules osseuses autour de l'implant, et donc de conserver une totale mobilité des vertèbres l'une par rapport à l'autre au cours du temps.

De préférence, ladite paroi intermédiaire est conformée de manière, lorsqu'elle n'est pas déformée, à maintenir lesdites parois latérales d'appui à une distance l'une de l'autre légèrement supérieure à la hauteur de l'espace intervertébral à restaurer.

Cette paroi intermédiaire est donc légèrement contrainte lorsque l'implant est mis en place et permet d'assurer, par rappel élastique, un léger soutien de la vertèbre supérieure par rapport à la vertèbre inférieure.

Avantageusement, l'implant est réalisé simplement par pliage d'une même pièce de matériau approprié, notamment d'un flan de tôle métallique. Le matériau utilisé peut notamment être l'alliage de titane, d'aluminium et de vanadium connu sous la référence "TA6V".

Selon une forme de réalisation préférée de l'invention, lesdits moyens de fixation de l'implant aux vertèbres comprennent au moins une série de nervures parallèles entre elles, à arêtes libres acérées, faisant saillie de la face extérieure de l'extrémité libre d'une paroi latérale d'appui.

Ces nervures sont destinées à venir s'insérer dans la zone antérieure du corps de la vertèbre adjacente.

L'implant peut comprendre deux séries de nervures, une sur l'une des parois latérales d'appui, l'autre sur l'autre paroi latérale d'appui. Pour le traitement de vertèbres cervicales, l'implant présente alors avantageusement une paroi latérale d'appui "inférieure", c'est-à-dire venant contre la vertèbre inférieure lors de la mise en place, ayant une longueur supérieure à l'autre paroi latérale d'appui.

L'implant décrit ci-dessus peut faire partie d'une gamme d'implants comprenant au moins un autre implant intervertébral, destiné à réaliser une fusion entre les deux vertèbres à traiter ; cet autre implant, dit ci-après "de fusion", présente une structure similaire à celle de l'implant décrit ci-dessus
5 mais comprend des moyens de fixation qui permettent son assemblage rigide autres vertèbres traitées.

De préférence, dans ce cas, lesdits moyens permettant la fixation de l'implant "de fusion" comprennent au moins une patte solidaire de l'une desdites parois latérales d'appui, percée d'un trou de réception d'une vis
10 d'ancrage, cette vis étant destinée à être insérée dans le corps de la vertèbre correspondante.

Lesdites parois latérales d'appui de l'implant "de fusion" peuvent présenter des revêtements de surface favorisant leur ostéo-intégration et/ou comprendre des trous qui mettent l'espace qu'elles délimitent entre elles en
15 communication avec l'extérieur de l'implant. Un greffon osseux peut alors être placé dans cet espace.

Pour sa bonne compréhension, l'invention est à nouveau décrite ci-dessous en référence au dessin schématique annexé, représentant, à titre d'exemple non limitatif, une forme de réalisation possible de l'implant
20 intervertébral qu'elle concerne, et un implant "de fusion" inclut dans une gamme d'implants qu'elle concerne également, cette gamme comprenant ledit implant intervertébral selon l'invention et ledit implant "de fusion".

La figure 1 est une vue en perspective de l'implant intervertébral qu'elle concerne ;
25 la figure 2 en est une vue de côté, après mise en place ;
la figure 3 est une vue en perspective dudit implant "de fusion", et
la figure 4 est une vue de côté de cet implant "de fusion", après mise en place.

Les figures 1 et 2 représentent un implant intervertébral 1 pour le
30 traitement de vertèbres cervicales 10 par voie d'abord antérieur.

Comme cela apparaît, l'implant 1 est réalisé par pliage d'une même pièce de matériau, et présente, vu de profil, c'est-à-dire dans le plan sagittal après implantation, une forme recourbée définissant deux parois latérales d'appui 2 et une paroi intermédiaire 3.

35 Ladite pièce de matériau est un flan de tôle en alliage de titane, d'aluminium et de vanadium connu sous la référence "TA6V".

Les parois latérales 2 présentent, vues de profil, des formes bombées sur la majeure partie de leur longueur, leurs convexités étant tournées vers l'extérieur de l'implant 1. Au niveau de leurs zones d'extrémité libre, ces parois latérales d'appui 2 présentent une forme rectiligne et
5 comportent chacune une série de nervures 4.

La paroi 2 "inférieure", c'est-à-dire venant contre la vertèbre inférieure lors de l'implantation, a une longueur supérieure à l'autre paroi 2.

La paroi intermédiaire 3 présente une forme courbe dont la convexité est tournée vers l'extérieur de l'implant. Comme cela apparaît
10 clairement, elle ne forme pas d'angles marqués avec les parois latérales d'appui 2, ces parois latérales d'appui 2 et cette paroi intermédiaire 3 ayant ainsi, vues de profil, une forme partiellement ovale, "en goutte d'eau".

La paroi intermédiaire 3 est par ailleurs déformable élastiquement entre une forme neutre, dans laquelle elle maintient normalement les parois 2 à
15 une distance l'une de l'autre légèrement supérieure à la hauteur de l'espace intervertébral à restaurer, et une forme contrainte, dans laquelle cette paroi 3 autorise le rapprochement des extrémités libres des deux parois 2. Ce rapprochement est tel qu'il permet de diminuer la hauteur de l'implant 1 de telle sorte que cette hauteur soit inférieure à la hauteur de l'espace intervertébral à
20 restaurer.

Les nervures 4 sont parallèles entre elles et font saillie de la zone d'extrémité libre de chaque paroi 2, vers l'extérieur de l'implant 1. Chacune d'elles est délimitée par une face antérieure perpendiculaire à la direction longitudinale de l'implant 1 et par une face postérieure inclinée, formant un
25 angle d'environ de 50° avec la face antérieure. Ces nervures 4 présentent ainsi des arêtes libres relativement acérées.

L'implant 1 représenté à titre d'exemple présente les dimensions suivantes :

- dimension maximale de l'implant dans le plan sagittal : environ
30 17 mm ;
- différence de longueur des parois 2 : environ 1 mm ;
- dimension de l'implant dans le plan frontal : environ 18 mm ;
- épaisseur dudit flan au niveau des parois 2 et de la paroi 3 : environ 1 mm ;
- 35 - épaisseur maximum de l'implant 1, au niveau des faces extérieures bombées des parois latérales 2 : environ 7 mm ;

- rayon de courbure de la moitié supérieure de la paroi intermédiaire 3 : environ 2,7 mm ;

- rayon de courbure de la moitié inférieure de la paroi intermédiaire 3 : environ 3,3 mm ;

5 - rayon de courbure de la zone bombée de la paroi latérale 2 supérieure : 10 mm ;

- rayon de courbure de la zone bombée de la paroi latérale 2 inférieure : environ 25 mm ;

En pratique, les parois 2 sont rapprochées l'une de l'autre par
10 déformation de la paroi 3, pour permettre l'insertion de l'implant 1 entre les plateaux vertébraux des deux vertèbres 10 à traiter, puis, une fois cette insertion réalisée, les parois 2 sont relâchées, ce qui les plaque contre ces plateaux vertébraux. Les nervures 4 sont insérées dans les plateaux
15 vertébraux ou tissus, c'est-à-dire autorisant une légère déformation de l'implant par rapport aux vertèbres lors du mouvement de ces vertèbres, tout en s'opposant à toute expulsion de l'implant.

La forme bombée des parois 2 permet à ces parois de s'adapter
précisément à la forme que présentent les faces respectives de ces plateaux
20 vertébraux, et assure une certaine rétention de l'implant entre les vertèbres 10. La contrainte élastique subsistant dans la paroi 3 permet de maintenir les nervures 4 insérées dans les vertèbres 10.

L'implant "de fusion" 11 montré sur les figures 3 et 4 présente une
structure similaire à celle de l'implant 1 décrit ci-dessus, sinon que les parois 2
25 comprennent deux pattes 5, solidaires d'elles et prolongeant leurs extrémités libres.

Chacune de ces pattes 5 est rattachée à l'extrémité de la paroi 2
qui la comporte par deux zones de raccordement latérales courbes, qui
permettent d'assurer une liaison parfaitement solide de cette patte 5 et de la
30 paroi 2, et est percée d'un trou de réception d'une vis d'ancrage 6. Cette vis 6 est destinée à être insérée dans le corps de la vertèbre 10 correspondante, comme le montre la figure 4.

Chaque patte 5 forme un angle de l'ordre de 120° avec la direction
antéro-postérieure générale de la paroi 2 à laquelle cette patte est rattachée, et
35 présente une épaisseur supérieure à celle du reste de l'implant 1. Cette épaisseur est d'environ 1,5 mm dans l'exemple représenté.

L'implant "de fusion" 11 est utilisé pour réaliser une fusion entre les deux vertèbres 10 à traiter.

5 Il apparaît de ce qui précède que l'invention apporte une amélioration déterminante à la technique antérieure, en fournissant un implant intervertébral permettant de parfaitement restaurer l'espace intervertébral, sans former un obstacle aux mouvements des vertèbres, sans induire de risques d'insertion dans les plateaux vertébraux ni de risque de fusion par croissance des cellules osseuses, en étant facile à implanter et en ayant une pérennité non sujette à caution.

10 Il va de soi que l'invention n'est pas limitée à la forme de réalisation décrite ci dessus à titre d'exemple mais qu'elle en embrasse au contraire toutes les variantes de réalisation couvertes par les revendications ci-annexées.

REVENDICATIONS

1 - Implant intervertébral (1), notamment destiné au traitement de
5 vertèbres cervicales (10) par voie d'abord antérieur, comprenant deux parois
latérales (2) d'appui contre les plateaux vertébraux et une paroi intermédiaire
(3) de raccordement de ces parois latérales d'appui, cet implant (1) étant
déformable élastiquement pour son insertion entre les vertèbres (10) à traiter et
10 pour permettre de restaurer une mobilité amortie de ces vertèbres (10), et
comportant des moyens (4) pour son assemblage à ces vertèbres (10) ;

implant (1) caractérisé en ce que :

- lesdites parois latérales d'appui (2) présentent, vues de profil, des
formes courbes avec leur convexité tournée vers l'extérieur de l'implant (1) ;

- ladite paroi intermédiaire (3) présente une forme courbe, avec sa
15 convexité tournée vers l'extérieur de l'implant (1), et est telle qu'elle ne forme
pas d'angles marqués avec lesdites parois latérales d'appui (2), ces parois
latérales d'appui (2) et cette paroi intermédiaire (3) ayant ainsi, vues de profil,
une forme partiellement ovale, "en goutte d'eau" ; et

- les moyens (4) de fixation de l'implant (1) aux vertèbres (10) sont
20 conçus pour permettre un assemblage non rigide de cet implant (1) à ces
vertèbres (10), c'est-à-dire autorisant une légère déformation de l'implant (1)
par rapport aux vertèbres (10) lors du mouvement de ces vertèbres.

2 - Implant (1) selon la revendication 1, caractérisé en ce que ladite
paroi intermédiaire (3) est conformée de manière, lorsqu'elle n'est pas
25 déformée, à maintenir lesdites parois latérales d'appui (2) à une distance l'une
de l'autre légèrement supérieure à la hauteur de l'espace intervertébral à
restaurer.

3 - Implant (1) selon la revendication 1 ou la revendication 2,
caractérisé en ce qu'il est réalisé par pliage d'une même pièce de matériau
30 approprié, notamment d'un flan de tôle métallique.

4 - Implant (1) selon la revendication 3, caractérisé en ce que le
matériau utilisé est l'alliage de titane, d'aluminium et de vanadium connu sous
la référence "TA6V".

5 - Implant (1) selon l'une des revendications 1 à 4, caractérisé en
35 ce que lesdits moyens permettant sa fixation comprennent au moins une série

de nervures (4) parallèles entre elles, à arêtes libres acérées, faisant saillie de la face extérieure de l'extrémité libre d'une paroi latérale d'appui (2).

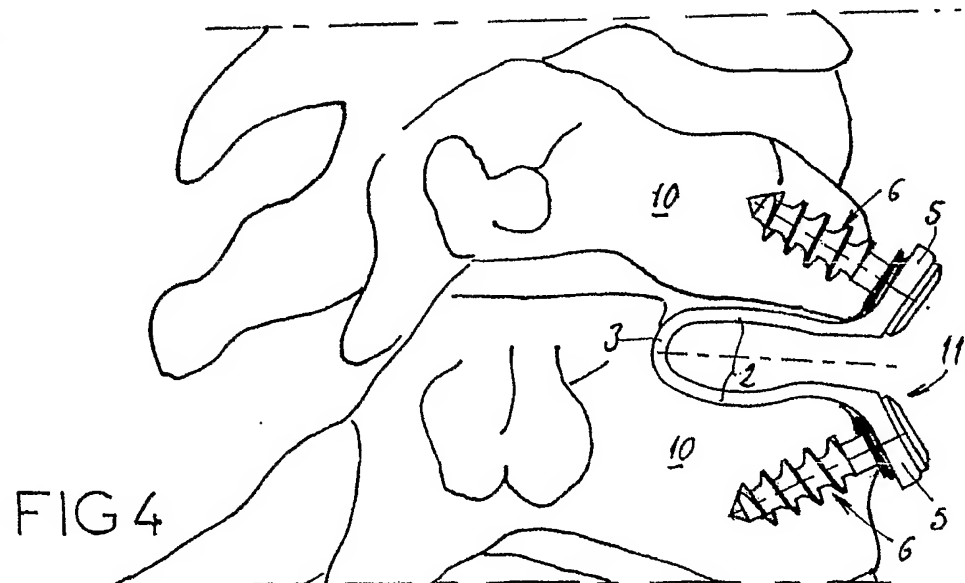
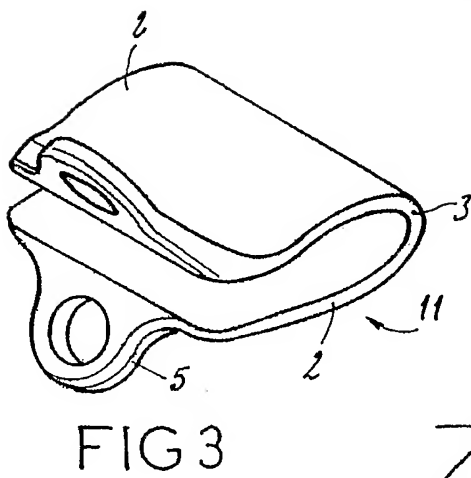
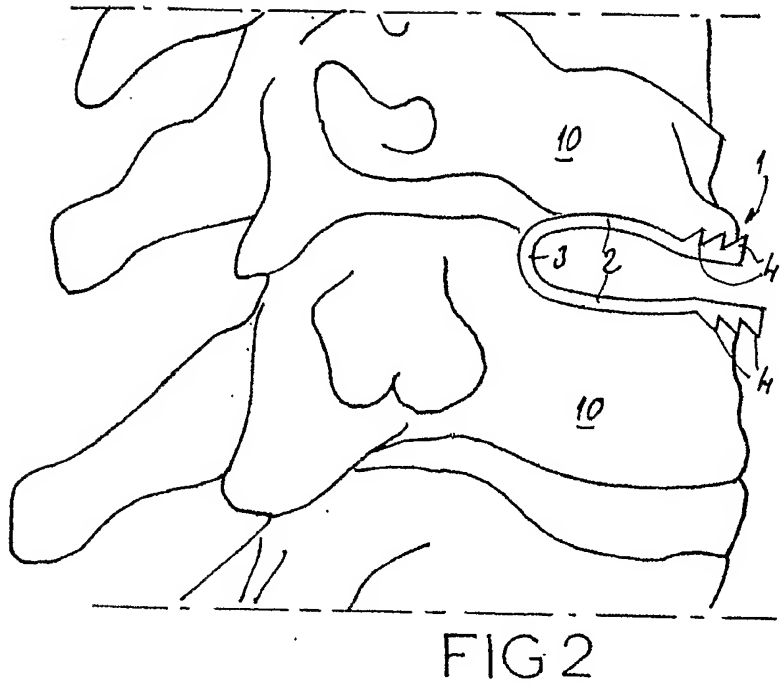
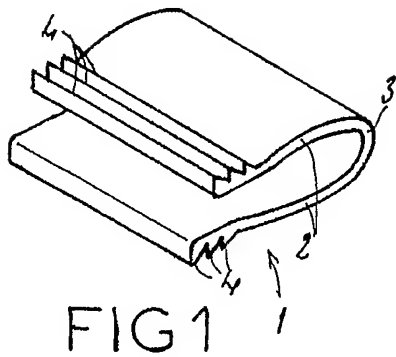
5 6 - Implant (1) selon la revendication 5, caractérisé en ce qu'il comprend deux séries de nervures (4), une sur l'une des parois latérales (2), l'autre sur l'autre paroi latérale (2) et en ce qu'il présente une paroi latérale (2) "inférieure", c'est-à-dire venant contre la vertèbre (10) inférieure lors de la mise en place, ayant une longueur supérieure à l'autre paroi latérale (2).

10 7 - Gamme d'implants comprenant au moins un implant intervertébral (1) selon l'une des revendications 1 à 6, caractérisée en ce qu'elle comprend au moins un autre implant intervertébral (11), destiné à réaliser une fusion entre les deux vertèbres (10) à traiter, cet autre implant (11), dit ci-après "de fusion", présentant une structure similaire à celle de l'implant (1) mais comprenant des moyens de fixation qui permettent son assemblage rigide autres vertèbres (10) traitées.

15 8 - Gamme d'implants selon la revendication 7, caractérisée en ce que lesdits moyens permettant la fixation de l'implant "de fusion" (11) comprennent au moins une patte (5) solidaire de l'une desdites parois latérales d'appui (2), percée d'un trou de réception d'une vis d'ancrage (6), cette vis (6) étant destinée à être insérée dans le corps de la vertèbre (10) correspondante.

20 9 - Gamme d'implants selon la revendication 7 ou la revendication 8, caractérisée en ce que lesdites parois latérales d'appui (2) de l'implant "de fusion" (11) présentent des revêtements de surface favorisant leur ostéo-intégration et/ou comprennent des trous qui mettent l'espace qu'elles délimitent entre elles en communication avec l'extérieur de l'implant (1).

25 10 - Gamme d'implants selon la revendication 9, caractérisée en ce que l'implant "de fusion" (11) reçoit un greffon osseux dans l'espace que lesdites parois latérales d'appui (2) délimitent entre elles.



INTERNATIONAL SEARCH REPORT

Internationale Application No

PCT/FR 03/00799

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 749 916 A (RICHELSON PHILIP) 12 May 1998 (1998-05-12) cited in the application claims 1,2,5,6,14-16,18,19; figures 2,5	1-5
A	---	7,9
X	WO 01 62190 A (HANSEN FREDERIC ;STRYKER SPINE SA (FR)) 30 August 2001 (2001-08-30) cited in the application claims 4,9,13,14; figures 1A,4-7 page 5, line 27 -page 6, line 14	1-4
A	---	7,8,10
A	FR 2 812 806 A (HENRY PATRICK PHILIBERT) 15 February 2002 (2002-02-15) claims 1,3; figures ---	1-4,9,10
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

Internationale Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 713 899 A (GODARD JOEL ET AL) 3 February 1998 (1998-02-03) figures column 2, line 41 - line 67 ---	1,3-5,7, 8,10
A	US 6 235 059 B1 (ALBY ALBERT ET AL) 22 May 2001 (2001-05-22) figures 1,2 column 2, line 35 -column 3, line 13 ---	1,4,7,8, 10
A	US 5 306 307 A (LARIVIERE RICHARD L ET AL) 26 April 1994 (1994-04-26) figures 3,4 column 5, line 60 -column 6, line 2 column 7, line 46 - line 54 ---	1,4,5,9
A	WO 00 04851 A (BRYAN VINCENT ;KUNZLER ALEX (US); SPINAL DYNAMICS CORP (US)) 3 February 2000 (2000-02-03) figures 1,4 page 4, line 5 - line 13 -----	1,5,7

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Internat Application No

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RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale No

PCT/FR 03/00799

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 7 A61F2/44

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)

CIB 7 A61F

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)

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C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
X	US 5 749 916 A (RICHELSOPH MARC) 12 mai 1998 (1998-05-12) cité dans la demande revendications 1,2,5,6,14-16,18,19; figures 2,5	1-5
A	---	7,9
X	WO 01 62190 A (HANSEN FREDERIC ;STRYKER SPINE SA (FR)) 30 août 2001 (2001-08-30) cité dans la demande revendications 4,9,13,14; figures 1A,4-7 page 5, ligne 27 -page 6, ligne 14	1-4
A	---	7,8,10
A	FR 2 812 806 A (HENRY PATRICK PHILIBERT) 15 février 2002 (2002-02-15) revendications 1,3; figures ---	1-4,9,10
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Date à laquelle la recherche internationale a été effectivement achevée

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C.(suite) DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	US 5 713 899 A (GODARD JOEL ET AL) 3 février 1998 (1998-02-03) figures colonne 2, ligne 41 - ligne 67 ----	1,3-5,7, 8,10
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A	US 5 306 307 A (LARIVIERE RICHARD L ET AL) 26 avril 1994 (1994-04-26) figures 3,4 colonne 5, ligne 60 - colonne 6, ligne 2 colonne 7, ligne 46 - ligne 54 ----	1,4,5,9
A	WO 00 04851 A (BRYAN VINCENT ; KUNZLER ALEX (US); SPINAL DYNAMICS CORP (US)) 3 février 2000 (2000-02-03) figures 1,4 page 4, ligne 5 - ligne 13 -----	1,5,7

RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale No

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			EP 1100416 A1	23-05-2001
			JP 2002521090 T	16-07-2002
			WO 0004851 A1	03-02-2000

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(74) Agents: **COLLIER, Douglas, A.**; Woodard, Emhardt, Moriarty, McNett & Henry LLP, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 et al. (US).

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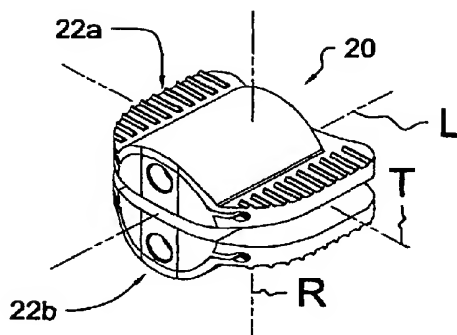
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[Continued on next page]

(54) Title: ARTICULAR DISC PROSTHESIS AND METHOD FOR IMPLANTING THE SAME



(57) **Abstract:** An articular disc prosthesis and method of implanting the same within an intervertebral space between adjacent vertebral bodies. The prosthesis includes a pair of articular components and an articular ball disposed therebetween. Each of the articular components includes an outer shell portion and a removable inner insert portion. The insert portion includes a concave articular surface sized and shaped to receive a portion of the articular ball to provide articulating motion between the articular components. The outer shell portion includes a central hemi-cylindrical portion, a pair of laterally extending flanges, and an axially extending lip. Following removal of the natural intervertebral disc, a pair of hemi-cylindrical recesses is formed along a central region of the adjacent vertebral bodies to a predetermined depth. The prosthesis is implanted within the prepared disc space by axially displacing the hemi-cylindrical central portions of the articular components along the hemi-cylindrical recesses in the vertebral bodies. The lateral flanges and the axial lip of the articular components bear against the endplates of the adjacent vertebral bodies to stabilize the prosthesis and to prevent subsidence.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ARTICULAR DISC PROSTHESIS AND METHOD FOR IMPLANTING THE SAME

CROSS REFERENCE TO RELATED APPLICATIONS

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The present application claims the benefit of Provisional Application Serial No. 60/375,354 filed on April 25, 2002, the contents of which are hereby incorporated by reference in their entirety.

FIELD OF THE INVENTION

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The present invention relates generally to the field of spinal implants, and more particularly relates to an articular disc prosthesis and method of implantation for use in the total or partial replacement of a natural intervertebral disc.

BACKGROUND OF THE INVENTION

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In the treatment of diseases, injuries or malformations affecting spinal motion segments, and especially those affecting disc tissue, it has long been known to remove some or all of a degenerated, ruptured or otherwise failing disc. In cases involving intervertebral disc tissue that has been removed or is otherwise absent from a spinal motion segment, corrective measures are indicated to insure the proper spacing of the vertebrae formerly separated by the removed disc tissue.

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In some instances, the two adjacent vertebrae are fused together using transplanted bone tissue, an artificial fusion component, or other compositions or devices. Spinal fusion procedures, however, have raised concerns in the medical community that the bio-mechanical rigidity of intervertebral fusion may predispose neighboring spinal motion segments to rapid deterioration. More specifically, unlike a natural intervertebral disc, spinal fusion prevents the fused vertebrae from pivoting and rotating with respect to one another. Such lack of mobility tends to increase stresses on adjacent spinal motion segments. Additionally, several conditions may develop within adjacent spinal motion segments, including disc degeneration, disc herniation, instability, spinal stenosis, spondylosis and facet joint arthritis. Consequently, many patients may require additional disc removal and/or another type of surgical procedure as a result of spinal fusion. Alternatives to spinal fusion are therefore desirable.

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Several different types of intervertebral disc arthroplasty devices have been proposed for preventing the collapse of the intervertebral space between adjacent vertebrae while maintaining a certain degree of stability and range of pivotal and rotational motion

therebetween. Such devices typically include two or more articular components that are attached to respective upper and lower vertebrae. The articular components are anchored to the upper and lower vertebrae by a number of methods, including the use of bone screws that pass through corresponding openings in each of the elements and thread into vertebral bone, and/or by the inclusion of spikes or teeth that penetrate the vertebral endplates to inhibit migration or expulsion of the device. The articular components are typically configured to allow the elements, and correspondingly the adjacent vertebrae, to pivot and/or rotate relative to one another.

As discussed above, prior intervertebral disc arthroplasty devices are relatively difficult to implant between adjacent vertebrae. To implant such devices, the adjacent vertebrae are spread apart a distance that is somewhat greater than the normal distance separating the vertebrae so that the device can be maneuvered between the vertebrae and the anchors can be engaged to the vertebral endplates. Such an operation presents a risk of injury to the vertebrae caused by misplacement and/or scratching of the vertebral endplates or other tissue by the anchors. Such operation also presents a risk of injury resulting from over-distraction of the intervertebral space. As also discussed above, other types of prior arthroplasty devices require the threading of bone screws or another type of fastener into the adjacent vertebrae. However, this type of anchoring method requires precise placement and orientation of the bone screws to provide adequate anchoring and to avoid injury to adjacent tissue or vertebral structures. Moreover, prior methods of implanting arthroplasty devices do not reliably position the device at the proper location within the intervertebral disc space.

The articular components associated with prior arthroplasty devices are also prone to wear, particularly in cases where the abutting surface area of the articular joint is relatively small. Generally, as the abutting surface area of an articular joint is reduced, contact stress is correspondingly increased which may reduce the overall life of the joint. As a result, worn out components must be periodically replaced to avoid malfunctioning or potential breakage of the arthroplasty device.

Thus, there is a general need in the industry to provide an improved articular disc prosthesis and a method of implanting the same than is currently available within the industry. The present invention meets this need and provides other benefits and advantages in a novel and unobvious manner.

SUMMARY OF THE INVENTION

The present invention relates generally to an articular disc prosthesis and a method of implanting the same. While the actual nature of the invention covered herein can only
5 be determined with reference to the claims appended hereto, certain forms of the invention that are characteristic of the preferred embodiments disclosed herein are described briefly as follows.

One form of the present invention is directed to an articular disc prosthesis, including a first articular component having a first bearing surface adapted to engage a
10 first vertebra, and a second articular component having second bearing surface adapted to engage a second vertebra, with the first and second bearing surfaces defining a space therebetween. At least one of the first and second articular components includes a concave articular surface that cooperates with a corresponding convex articular surface to provide articulating motion between the first and second articular components, with
15 at least a portion of the concave articular surface extending beyond the space between the first and second bearing surfaces.

Another form of the present invention is directed to an articular disc prosthesis for replacement of a natural intervertebral disc, including a first articular component defining a first concave articular surface, a second articular component defining a
20 second concave articular surface, and an articular ball positioned between the first and second concave articular surfaces to provide articulating motion between the first and second articular components, and wherein the articular ball has a diameter greater than a height of the natural intervertebral disc.

25 Another form of the present invention is directed to an articular disc prosthesis, including a first articular component adapted to engage a first vertebra, a second articular component adapted to engage a second vertebra, and wherein each of the first and second articular components extends along an axis and includes a central axial portion defining a convex lateral curvature and a pair of flanges extending laterally
30 from the central axial portion in generally opposite directions.

Another form of the present invention is directed to an articular disc prosthesis, including first and second modular articular components, with each of the modular

articular components having an outer shell portion configured to engage a corresponding one of first and second vertebrae, and an inner insert portion removably engaged with the outer shell portion. The inner insert portion includes an articular surface cooperating with a corresponding articular surface to provide articulating motion between the first and second modular articular components.

Another form of the present invention is directed to a method of implanting an articular disc prosthesis between first and second vertebrae, including providing an articular disc prosthesis having a first articular component adapted to engage a first vertebra and a second articular component adapted to engage a second vertebra, with each of the first and second articular components extending along an axis and including a central axial portion defining a convex lateral curvature and a pair of flanges extending laterally from the central axial portion in generally opposite directions. The method further includes removing at least a portion of a natural intervertebral disc from between the first and second vertebrae to form an intervertebral space, forming an elongate recess along a central region of each of the first and second vertebrae, and implanting the articular disc prosthesis within the intervertebral space by inserting the central axial portions of the first and second articular components within the elongate recesses formed along the first and second vertebrae.

It is one object of the present invention to provide an improved articular disc prosthesis. It is another object of the present invention to provide an improved method of implanting an articular disc prosthesis within the intervertebral disc space between adjacent vertebral bodies.

Further objects, features, advantages, benefits, and aspects of the present invention will become apparent from the drawings and description contained herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an articular disc prosthesis according to one form of the present invention.

5 FIG. 2 is a front elevational view of the articular disc prosthesis illustrated in FIG. 1.

FIG. 3 is a side elevational view of the articular disc prosthesis illustrated in FIG. 1.

10 FIG. 4 is an exploded perspective view of the articular disc prosthesis illustrated in FIG. 1.

FIG. 5 is a top view of an endplate according to one embodiment of the present invention for use with the articular disc prosthesis illustrated in FIG. 1.

FIG. 6 is an end view of the endplate illustrated in FIG. 5.

FIG. 7 is a side view of the endplate illustrated in FIG. 5.

15 FIG. 8 is a sectional view of the endplate illustrated in FIG. 5, taken along line 8-8 of FIG. 5.

FIG. 9 is an end view of an insert according to one embodiment of the present invention for use with the articular disc prosthesis illustrated in FIG. 1.

FIG. 10 is a top view of the insert illustrated in FIG. 9.

20 FIG. 11 is a side view of the insert illustrated in FIG. 10.

FIG. 12 is a sectional view of the insert illustrated in FIG. 9, taken along line 12-12 of FIG. 9.

FIG. 13 is a lateral view of a portion of the spinal column, illustrating a pair of adjacent upper and lower vertebrae separated by a natural intervertebral disc.

25 FIG. 14 is an anterior view of the portion of the spinal column shown in FIG. 13, illustrating the removal of portions of the upper and lower vertebrae to accommodate insertion of the articular disc prosthesis illustrated in FIG. 1 therebetween.

FIG. 15 is a lateral view of the portion of the spinal column shown in FIG. 14.

30 FIG. 16 is an anterior view of the portion of the spinal column shown in FIG. 14, illustrating implantation of the articular disc prosthesis between the upper and lower vertebrae.

FIG. 17 is a partial sectional view of the portion of the spinal column shown in FIG. 16, illustrating implantation of the articular disc prosthesis between the upper and lower vertebrae.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no
5 limitation of the scope of the invention is hereby intended, and that any alterations and further modifications in the illustrated devices, and any further applications of the principles of the invention as illustrated herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring to FIGS. 1-4, shown therein is an articular disc prosthesis 20
10 according to one form of the present invention. The disc prosthesis 20 extends generally along a longitudinal axis L and includes an upper articular component 22a, a lower articular component 22b, and an articular ball 24 disposed between the upper and lower articular components 22a, 22b. The articular ball 24 defines a convex articular surface 25 and preferably has a spherical configuration. However, it should be
15 understood that the articular ball 24 may take on other configurations as well, such as, for example, an elliptical or eccentric configuration.

The articular components 22a, 22b are configured substantially identical to one another. Therefore, the description and/or illustration of one of the articular components 22a, 22b applies equally to the other. In a preferred embodiment of the
20 invention, the articular components 22a, 22b have a modular configuration. More specifically, each of the articular components 22a, 22b preferably includes an outer shell or endplate 26 and an inner articular cup or insert 28. As will be discussed in further detail below, the articular insert 28 can be removed from the endplate 26 and replaced with an insert of the same type or of a different type. The articular insert 28 is
25 secured in position relative to the endplate 26 by a first set of fasteners 30. A second set of fasteners 32 is preferably included to engage the first set of fasteners to prevent the first set of fasteners 30 from loosening and backing out. In one embodiment of the invention, the fasteners 30, 32 are threaded set screws. However, it should be
30 understood that other types and configurations of fasteners are also contemplated as would occur to one of ordinary skill in the art.

The upper and lower articular components 22a, 22b and the articular ball 24 cooperate to form an articulating joint that is sized and configured for disposition

within an intervertebral disc space between adjacent vertebral bodies. Specifically, the convex outer surface 25 of the articular ball 24 cooperates with corresponding concave surfaces formed in the articular inserts 28 to provide relative articulating motion between the articular components 22a, 22b. In a preferred embodiment of the invention, such articulating motion includes both pivotal and rotational movement to maintain or restore motion substantially similar to normal bio-mechanical motion provided by a natural intervertebral disc.

In one embodiment of the invention, the articular components 22a, 22b are permitted to rotate relative to one another about a rotational axis R. In another embodiment of the invention, the articular components 22a, 22b are permitted to pivot relative to one another about a number of axes, including lateral or side-to-side pivotal movement about the longitudinal axis L and anterior-posterior pivotal movement about a transverse axis T. In a further embodiment of the invention, the articular components 22a, 22b are permitted to pivot relative to one another about any axis which lies in a plane that intersects the longitudinal axis L and the transverse axis T. Although the disc prosthesis 20 has been illustrated and described as providing a combination of various articulating movements, it should be understood that other variations and combinations of articulating movements are also contemplated as falling within the scope of the present invention. It should also be understood that other types of articulating movement are also contemplated, such as, for example, relative translational or linear movement.

Although the various components of the articular disc prosthesis 20 may be formed from a wide variety of materials, following is a listing of various component materials according to one embodiment of the present invention. It should be understood, however, that the components of the disc prosthesis 20 may be formed of materials other than those specifically listed below, including any bio-compatible material that would be known to one of ordinary skill in the art or any other equivalent material.

The outer endplates 26 are preferably formed of a polymeric material, such as, for example, a polyaryletherketone polymer or polyethylene. In other embodiments of the invention, the outer endplates 26 may be formed of titanium, stainless steel, other types of metallic materials, or a ceramic material. The outer surfaces of the endplate 26

that are intended to be in direct contact with vertebral bone are preferably coated with a bone-growth promoting substance, such as, for example, a hydroxyapatite (HA) coating formed of calcium phosphate. The articular inserts 28 are preferably formed of a metallic material, such as, for example, cobalt-chrome-molybdenum metallic alloy (ASTM F-799 or F-75). In other embodiments of the invention, the articular inserts 28 may be formed of other types of metallic materials, such as, for example, titanium or stainless steel, a ceramic material, or a polymeric material. The articular ball 24 is preferably formed of a polymeric material, such as, for example, an ultra-high molecular weight polyethylene (UHMWPE). In another embodiment of the invention, the articular ball 24 may be cross-linked by radiation, by chemical means or by any other method known to those of skill in the art. In other embodiments of the invention, the articular ball 24 may be formed of titanium, stainless steel, other types of metallic materials, or a ceramic material. In one embodiment of the invention, the first set of fasteners 30 is formed of a polymeric material, such as, for example, a polyaryletherketone polymer. Preferably, the first set of fasteners 30 is formed of the same material as the endplates 26. In another embodiment of the invention, the second set of fasteners 32 is formed of a metallic material, such as, for example, cobalt-chrome-molybdenum metallic alloy. Preferably, the second set of fasteners 32 is formed of the same material as the articular inserts 28. In other embodiments of the invention, the first and second sets of fasteners 30, 32 may be formed of other types of materials, such as, for example, titanium, stainless steel, other types of metallic materials, a ceramic material, or a polymeric material.

Referring to FIGS. 5-8, shown therein are various details regarding the configuration of the outer endplates 26. In one embodiment of the invention, the endplates 26 are each comprised of a central axial portion 50 and a lip portion 52 extending about a periphery of the axial portion 50. The peripheral lip portion 52 is comprised of a pair of flanges or wings 54, 56 extending laterally from the central portion 50, and a flange or lip 58 extending axially from the central portion 50. As shown in FIG. 5, the outer peripheral profile of the endplate 50 is preferably sized and shaped to substantially correspond to the size and shape of the vertebral endplate of an adjacent vertebra.

In one embodiment of the invention, the central axial portion 50 has a hemi-

cylindrical configuration, including an outer surface 60 defining a convex lateral curvature extending along an axial length l . It should be understood, however, that the central axial portion 50 may take on other configurations, including other types of arcuate configurations, a rectangular configuration, or various types of polygonal configurations. It should also be understood that the convex outer surface 60 may take on other shapes, including an hemi-elliptical shape or other types of arcuate and/or polygonal configurations. The axial portion 50 includes an open axial end 62, a closed axial end 64, and a concave inner surface 66. The concave inner surface 66 defines a cavity 68 extending axially between the open and closed ends 62, 64. As will be discussed below, the cavity 68 is sized and shaped to receive a corresponding portion of the articular insert 28 therein. In one embodiment of the invention, the cavity 68 has a hemi-cylindrical configuration. However, it should be understood that the cavity 68 may take on other configurations as well, including other types of arcuate configurations, a rectangular configuration, or other types of polygonal configurations.

The lateral flanges 54, 56 each include an outwardly facing bearing surface 70 and an inwardly facing surface 72. In one embodiment of the invention, the outwardly facing bearing surface 70 is contiguous with the hemi-cylindrical outer surface 60 of the central axial portion 50. Similarly, the inwardly facing surface 72 is contiguous with the hemi-cylindrical inner surface 66 of the central axial portion 50. It should be understood, however, that other positions and orientations of the lateral flanges 54, 56 relative to the central axial portion 50 are also contemplated as falling within the scope of the present invention.

The outwardly facing bearing surface 70 preferably defines a number of anchor elements configured to engage vertebral bone. In one embodiment of the invention, the outwardly facing bearing surface 70 defines a number of projections or teeth 74. The teeth 74 are preferably triangular-shaped, defining pointed tips configured to bite into and securely grip vertebral bone. However, it should be understood that other configurations of the teeth 74 are also contemplated as would occur to one of skill in the art. It should also be understood that other types and configurations of anchor elements are also contemplated, such as, for example, spikes, protrusions, or various types of surface roughening features to aid in gripping vertebral bone to inhibit migration or expulsion of the disc prosthesis 20. In the illustrated embodiment of the

invention, the teeth 74 extend laterally across a substantial portion of the width of flanges 54, 56 and are positioned intermittently along the length of the flange 54, 56. However, in another embodiment of the invention, the teeth 74 may extend along the length of the flange 54, 56 and may be positioned intermittently along the width of the flange 54, 56. It should also be understood that other positions and orientations of the teeth 74 are also contemplated as falling within the scope of the present invention.

In one embodiment of the invention, each of the lateral flanges 54, 56 has a first end 80, a second end 82, and an axial passage 84 extending from the first end 80 toward the second end 82. The axial passage 84 is disposed in communication with the hollow cavity 68 defined by the central axial portion 50, the purpose of which will be discussed below. In one embodiment, the axial passage 84 includes a circular portion 86 and a slot portion 88, with the slot portion 88 extending between the hollow cavity 68 and the circular portion 86. Internal threads 87 are preferably defined along a length of the circular portion 86 of axial passage 84 which are configured to threadingly receive the first and second sets of fasteners 30, 32.

The axial lip 58 includes an outwardly facing surface 90 and an inwardly facing surface 92. In one embodiment of the invention, the outwardly facing surface 92 is substantially flat. However, it should be understood the outwardly facing surface 92 could alternatively define a number of anchor elements configured to engage vertebral bone. The axial lip 58 includes an axially facing end surface 94 extending between the lateral flanges 54, 56. In one embodiment, the axially facing end surface 94 defines a recessed area 96 extending inwardly toward the central portion 50, the purpose of which will become apparent below. The recessed area 96 preferably has an arcuate configuration; however, other configurations are also contemplated as would occur to one of skill in the art.

As illustrated in FIGS. 6 and 8, in one embodiment of the invention, the inwardly facing surfaces 72 of the lateral flanges 54, 56 preferably define an outward taper arranged at a taper angle α . The outward taper preferably extends in a lateral direction along the entire length of the flanges 54, 56 (as shown in FIG. 6).

Additionally, at least the end portions of the inwardly facing surface 72 adjacent the ends 80, 82 are preferably tapered in an axial direction at a taper angle α . (as shown in FIG. 8). The inwardly facing surface 92 of the axial lip 58 also preferably defines an

outward taper extending in an axial direction at a taper angle α . As should be appreciated, the inwardly facing surfaces 72, 92 of the lateral flanges 54, 56 and the axial lip 58 cooperate to define a substantially conically-shaped surface surrounding the central axial portion 50 and extending outwardly relative to the rotational axis R at the taper angle α . In this manner, relative pivotal movement between the articular components 22a, 22b is limited to a predetermined range of motion via abutment of the inwardly facing surfaces 72, 92 of one of the endplate 26 against the inwardly facing surfaces 72, 92 of the opposing endplate 26.

In one embodiment of the invention, the taper angle α falls within a range of between about 5 degrees and about 15 degrees, thereby limiting relative pivotal motion between the articular components 22a, 22b within a range of just over 10 degrees to just over 30 degrees. In a more specific embodiment, the taper angle α is about 7.5 degrees, thereby limiting relative pivotal motion between the articular components 22a, 22b to just over 15 degrees. It should be understood, however, that the taper angle α may take on other values to satisfy the specific articular requirements of the disc prosthesis 20, including taper angles α less than 5 degrees and greater than 15 degrees. It should also be understood that the taper angle α need not necessarily be uniform, but may instead be varied to limit relative pivotal motion between the articular components 22a, 22b within different ranges depending upon the particular pivotal axis about which the articular components 22a, 22b are being pivoted. In the illustrated embodiment of the invention, each of the endplates 26 of the articular components 22a, 22b define outwardly tapering surfaces 72, 92. However, it should be understood that in another embodiment of the invention, only one of the endplates 26 defines outwardly tapering surfaces 72, 92, with the other endplate 26 defining substantially flat inwardly facing surfaces 72, 92. In a further embodiment of the invention, both of the endplates 26 define substantially flat inwardly facing surfaces 72, 92.

Referring to FIGS. 9-12, shown therein are various details regarding the configuration of the inner articular inserts 28. In one embodiment of the invention, the articular inserts 28 are each comprised of a central body 100 and a pair of splines 102, 104 extending laterally from the central body 100. The central body 100 preferably has a shape and configuration that corresponds to the shape and configuration of the inner cavity 68 of the endplate 26. In one embodiment, the central body 100 includes a

convex outer surface 106 that corresponds to the concave inner surface 66 of the endplate 26. The central body 100 also includes a relatively flat inner surface 108 disposed generally opposite the convex outer surface 106, and a pair of opposite axial end surfaces 110, 112. An axial opening 124 is preferably formed through the end surface 112 which is configured to receive a portion of an insertion instrument or tool therein (not shown). As illustrated in FIG. 10, the central body 100 has a hemi-cylindrical configuration that closely corresponds to the hemi-cylindrical configuration of the inner cavity 68 of the endplate 26. It should be understood, however, that the central body 100 may take on other configurations, including other types of arcuate configurations, a rectangular configuration, or various types of polygonal configurations.

The central body 100 includes a relatively large recess or socket 120 extending from the flat inner surface 108. The socket 120 defines a concave articular surface 122 that cooperates with the convex articular surface 25 of the ball 24 to provide articulating motion between the articular components 22a, 22b. More particularly, the ball 24 is at least partially disposed within the socket 120 such that the convex and concave articular surfaces 25, 122 are positioned in abutment to allow pivotal and rotational movement therebetween. In a preferred embodiment of the invention, the socket 120 is shaped and configured to closely correspond to the shape and configuration of the articular ball 24. In a one embodiment, the convex surface 25 of the ball 24 has a radius that is substantially equal to the radius of curvature of the concave surface 122 of socket 120. However, it should be understood that the radius of the articular ball 24 may be sized somewhat smaller than the radius of curvature of the socket 120. In one embodiment of the invention, the diameter of the articular ball 24 falls within a range of about 10 mm to about 30 mm. In a more specific embodiment, the diameter of the articular ball 24 is approximately 19 mm. Notably, since the area of abutment between the convex surface 25 of the articular ball 24 and the concave surface 122 of the socket 120 is relatively large, internal stresses within the disc prosthesis 20 are spread out over an increased surface area, thereby resulting in decreased wear and prolonged design life of the articular ball 24 and/or the articular inserts 28. Moreover, reducing internal stresses within the disc prosthesis 20 provides

an opportunity to form the articular ball 24 and/or the articular inserts 28 from non-metallic materials, such as, for example, a polymeric material or a ceramic material.

Although the articular ball 24 and the socket 120 are illustrated as having generally smooth, uninterrupted abutting articular surfaces 25, 122, it should be understood that in other embodiments of the invention, either or both of the articular surfaces 25, 122 may define one or more surface depressions to facilitate removal of matter disposed between abutting portions of the articular surfaces. Such surface depressions may include, for example, grooves, channels, passages, openings, flattened areas, or dimples. Further details regarding the inclusion of surface depressions on either or both of the articular surfaces 25, 122 are disclosed in co-pending U.S. Patent Application Serial No. 10/042,589, filed on January 9, 2002 and entitled "Intervertebral Prosthetic Joint", the contents of which are hereby expressly incorporated by reference in their entirety.

The splines 102, 104 extending from the central body 100 are shaped and configured to be received within the axial passages 84 extending through the flanges 54, 56 of the endplate 26. Each of the splines 102, 104 preferably includes a first axial portion 130 and a second axial portion 132. The first axial portion 130 has a lateral width that is somewhat greater than the lateral width of the second axial portion 132 so as to form an axially facing shoulder 134, the purpose of which will be discussed below. As shown in FIGS. 6 and 9, the overall axial profile of the articular insert 28 substantially corresponds to that of the cavity 68 and the axial passages 84 defined within the endplate 26.

Referring once again to FIG. 4, the articular components 22a, 22b of the disc prosthesis 20 are assembled by engaging the articular inserts 28 with the endplates 26. More specifically, the articular insert 28 is axially inserted into the endplate 26, with the central body 100 and the splines 102, 104 of the insert 28 being slidably displaced along the central cavity 68 and the axial passages 84 of the endplate 26. The articular insert 28 is retained within the endplate 26 by way of the first set of set screws 30. The set screws 30 are threadingly engaged along the threaded portion 87 of the axial passage 84 until tightly engaged against the axial shoulder 134 of the splines 102, 104. The second set of set screws 32 are then threadingly engaged along the threaded portion 87 of the axial passage 84 until the set screws 32 engage the first set of set screws 30.

The second set of set screws 32 serve to prevent the first set of set screws 30 from loosening and backing out. Once the articular components 22a, 22b have been assembled, the articular ball 24 is positioned within the sockets 120 defined by the articular inserts 28 to form the articulating disc prosthesis 20.

5 It should be appreciated that the modular nature of the disc prosthesis 20 offers several advantages. For example, if either of the articular components 22a, 22b or the articular ball 24 begins to malfunction or exhibits signs of wear, the disc prosthesis 20 can be easily disassembled by simply removing the set screws 30, 32 and sliding the articular inserts 28 and the articular ball 24 out from the endplates 26. Notably,
10 removal of the articular inserts 28 and the articular ball 24 can be done *in situ* without having to remove the endplates 26 from the intervertebral disc space. This is particularly advantageous if bone on-growth onto the endplates 26 has already commenced, thereby avoiding having to break the bony engagement between the endplates 26 and adjacent vertebral bone.

15 The modular nature of the disc prosthesis 20 also allows the articulating characteristics and movements to be revised without having to remove the entire disc prosthesis 20 from the intervertebral disc space. Notably, the articular components 22a, 22b and the articular ball 24 originally implanted within the intervertebral disc space can be removed from the endplates 26 and replaced with different types/configurations
20 of articular inserts 28 and/or a different articular ball 24 designed to provide the disc prosthesis 20 with modified articulating characteristics and movements. Once again, removal of the articular inserts 28 and the articular ball 24 can be done *in situ* without removing the endplates 26 from the intervertebral disc space. Additionally, the articular components 22a, 22b and the articular ball 24 may be removed from the
25 endplates 26 and replaced with a rigid spacer element to provide rigid stabilization between the adjacent vertebrae, or by a semi-rigid or flexible spacer element to provide flexible stabilization between the adjacent vertebrae.

Referring to FIG. 13, shown therein is a lateral view of a portion of the spinal column, illustrating a pair of adjacent upper and lower vertebrae V_U , V_L separated by a
30 natural intervertebral disc D. As discussed above, in cases where the natural intervertebral disc D is diseased or degenerated, most if not all of the natural disc D is

typically removed via a discectomy or a similar surgical procedure, the details of which would be known to one of ordinary skill in the art.

As illustrated in FIGS. 14 and 15, removal of the diseased or degenerated disc D results in the formation of an intervertebral disc space S between the upper and lower vertebrae V_U , V_L . To accommodate for the insertion of the disc prosthesis 20 within the intervertebral disc space S, preparation of the upper and lower vertebrae V_U , V_L is required. In one embodiment of the invention, the intervertebral space S is enlarged by forming elongate openings or recesses 300 along the inferior and superior portions of the upper and lower vertebrae V_U , V_L , respectively. The elongate recesses 300 preferably have a shape and configuration that substantially corresponds to the outer profile of the central axial portions 50 of the articular components 22a, 22b. In one embodiment, the elongate recesses 300 have a hemi-cylindrical shape; however, other shapes and configurations of the recesses 300 are also contemplated as would occur to one of skill in the art, including other types of arcuate configurations, a rectangular configuration, or other types of polygonal configurations.

In one embodiment of the invention, the elongate recesses 300 extend from an anterior side 302 of the vertebrae V_U , V_L toward a posterior side 304 of the vertebrae V_U , V_L to a predetermined depth d . In a preferred embodiment of the invention, the predetermined depth d of the elongate recesses 300 is approximately equal to or slightly greater than the length l of the central axial portions 50 of the articular components 22a, 22b. As will be discussed in further detail below, forming the recesses 300 at a predetermined depth d correspondingly controls the insertion depth of the disc prosthesis 20 to ensure proper positioning of the disc prosthesis 20 within the intervertebral disc space S. In one embodiment of the invention, the elongate recesses 300 are formed by reaming. However, other methods of forming the recesses 300 are also contemplated as would occur to one of ordinary skill in the art, such as, for example, by drilling, chiseling or curetting.

Referring to FIGS. 16 and 17, following preparation of the upper and lower vertebrae V_U , V_L , the disc prosthesis 20 may then be implanted within the intervertebral disc space S. In one embodiment of the invention, implantation is accomplished by inserting the cylindrical axial portions 50 of the articular components 22a, 22b within the elongate recesses 300, with the bearing surfaces of the lateral flanges 54, 56 and the

axial lip 58 facing the vertebral endplates of the upper and lower vertebrae V_U , V_L . The end surface 94 of the axial lip 58 faces a posterior direction, with the recessed area 96 defined by the axial lip 58 (FIG. 5) providing sufficient clearance to avoid encroachment into the area adjacent the spinal canal.

5 Prior to implantation of the disc prosthesis 20 within the intervertebral disc space S, the articular components 22a, 22b are preferably placed in a predetermined relationship with respect to one another. In one embodiment of the invention, an insertion instrument (not shown) may be used to position and secure the articular components 22a, 22b at a predetermined spacing and at a predetermined orientation
10 relative to one another. The insertion instrument would maintain the articular components 22a, 22b at the predetermined spacing and orientation during manipulation of the disc prosthesis 20, and would be capable of selectively releasing the disc prosthesis 20 once properly positioned within the intervertebral disc space S. Such insertion instrument may include, for example, a pair of prongs adapted for insertion
15 within the axial openings 124 formed in the articular inserts 28 of the articular components 22a, 22b.

As should be appreciated, the specific angular relationship between the articular component 22a, 22b is dictated by the geometry of the upper and lower vertebrae V_U , V_L and the particular curvature or lordosis of the portion of the spinal column being
20 treated. As such, the relative angular orientation of the planes P_1 and P_2 defined along the bearing surfaces 70 of the endplate flanges 54, 56 should correspond to the particular geometric configuration of the natural intervertebral disc D. As should also be appreciated, the distance between the planes P_1 and P_2 should be approximately equal to the height of the natural intervertebral disc D. Additionally, although the
25 bearing surfaces 70 of the endplate flanges 54, 56 have been illustrated and described as having a substantially planar configuration, it should be understood that the bearing surfaces 70 may take on other configurations. For example, the bearing surfaces 70 may take on a curved or arcuate configuration that corresponds to the particular contour of the adjacent vertebral endplate against which the bearing surfaces 70 are engaged.

30 In one embodiment of the invention, the disc prosthesis 20 is inserted between the upper and lower vertebrae V_U , V_L in a direction generally parallel to its longitudinal axis L, with the central axial portions 50 of the endplates 26 being axially displaced

through the elongate recesses 300. Notably, since the central axial portions 50 are axially displaced through the preformed recesses 300, distraction of the upper and lower vertebrae V_U , V_L to accommodate insertion of the disc prosthesis 20 is minimized, if not eliminated entirely. In the illustrated embodiment of the invention, the disc prosthesis 20 is inserted into the intervertebral disc space S via an anterior approach. However, it should be understood that the elongate recesses 300 may alternatively extend from the posterior side 304 of the vertebrae V_U , V_L toward the anterior side 302 at a predetermined depth d to accommodate insertion of the disc prosthesis 20 into the intervertebral disc space S via a posterior approach. It should also be understood that the elongate recesses 300 may alternatively extend from a first lateral side of the vertebrae V_U , V_L toward an opposite lateral side of the vertebrae at a predetermined depth d to accommodate insertion of the disc prosthesis 20 into the intervertebral disc space S via a lateral approach.

As discussed above, the depth d of the elongate recesses 300 is approximately equal to or slightly greater than the length l of the central axial portions 50 of the endplates 26. Accordingly, precise position of the disc prosthesis 20 within the intervertebral disc space S is possible. Specifically, proper axial positioning of the disc prosthesis 20 is accomplished when the insertion ends 64 of the central axial portions 50 bottom out against the axially facing end surfaces 301 of the elongate recesses 300. Controlling the insertion depth of the disc prosthesis 20 results in more precise positioning to avoid over-insertion or under-insertion of the disc prosthesis 20. Additionally, disposition of the central axial portions 50 within the elongate recesses 300 substantially prevents lateral and/or rotational movement of the articular components 22a, 22b with respect to the upper and lower vertebrae V_U , V_L . The relatively large surface area of the central axial portions 50 contacting the upper and lower vertebrae V_U , V_L also tends to minimize subsidence into the cancellous bone. Moreover, engagement of the bearing surfaces of the lateral flanges 54, 56 and the axial lip 58 against the upper and lower vertebrae V_U , V_L tends to minimize subsidence of the disc prosthesis 20 into the cancellous bone.

Once the articular components 22a, 22b are properly positioned within the intervertebral disc space S, the axial lip 58 of the endplates 26 will bear against the posterior cortical rim of the upper and lower vertebrae V_U , V_L . Additionally, the

anterior ends of the central axial portions 50 will bear against the anterior cortical rim of the upper and lower vertebrae V_U , V_L . Moreover, the lateral flanges 54, 56 may be configured to bear against the lateral cortical rim and/or the anterior cortical rim of the upper and lower vertebrae V_U , V_L . Such bearing engagement between the endplates 26 of the articular components 22a, 22b and the outer rim of the upper and lower vertebrae V_U , V_L provides additional stabilization of the disc prosthesis 20 and tends to minimize subsidence. Additionally, the teeth 74 formed along the lateral flanges 54, 56 grip the bony endplates of the upper and lower vertebrae V_U , V_L to resist migration of the disc prosthesis 20 and/or to prevent expulsion of the disc prosthesis 20 from the intervertebral disc space S.

The disc prosthesis 20 is initially maintained in position within the intervertebral disc space S relative to the upper and lower vertebrae V_U , V_L via disposition of the central axial portions 50 within the elongate recesses 300 and by engagement of the teeth 74 against the bony vertebral endplates. However, over time the disc prosthesis 20 will be further secured to the upper and lower vertebrae V_U , V_L via bony on-growth onto the surfaces of the articular components 22a, 22b that are in contact with vertebral bone tissue, particularly those surfaces which are in contact with metabolically active cancellous bone. Such bony on-growth provides further resistance to migration of the disc prosthesis 20 and possible expulsion from the intervertebral disc space S. It should be understood that other means for engaging the disc prosthesis 20 to the upper and lower vertebrae V_U , V_L are also contemplated, such as, for example, bone screws, staples, an adhesive, or by other methods of engagement that would occur to one of ordinary skill in the art.

In use, the articular components 22a, 22b and the articular ball 24 cooperate to provide a ball-and-socket type joint that permits relative pivotal and rotational movement between the articular components 22a, 22b, which correspondingly permits relative pivotal and rotational movement between the upper and lower vertebrae V_U , V_L . More specifically, the spherical surface 25 of the articular ball 24 is slidably engaged against the concave surfaces 122 of the articular inserts 28. The resulting pivotal and rotational movement of the articular components 22a, 22b serves to maintain or restore articular motion to the portion of the spinal column being treated

that is substantially similar to the normal bio-mechanical motion provided by a natural intervertebral disc D.

As shown in FIGS. 16 and 17, the unique geometry of the articular components 22a, 22b allows the use of a relatively large articular ball 24. As discussed above, use of an articular ball 24 having a large diameter increases the area of abutment between the convex surface 25 of the ball 24 and the concave surface 122 of the socket 120. As a result, internal stresses within the disc prosthesis 20 are reduced, thereby resulting in decreased wear and prolonged design life of the disc prosthesis 20. Use of a relatively large diameter articular ball 24 is made possible by the hemi-cylindrical central portions 50 of the endplates 26 which are positioned within the hemi-cylindrical recesses 300 formed along the upper and lower vertebrae V_U , V_L . Notably, this unique geometric design allows the use of an articular ball 24 having a diameter greater than the height of the natural intervertebral disc D. As a result, at least a portion of the abutting articular surfaces 25, 122 of the ball 24 and the articular insert 28 is positioned beyond the intervertebral disc space defined between the planes P_1 and P_2 extending along the bearing surfaces 70 of the endplate flanges 54, 56.

Although the disc prosthesis 20 has been illustrated and described as including a pair of articular components 22a, 22b having a separate articular ball 24 disposed therebetween, in an alternative embodiment of the invention the articular ball 24 may be replaced by a protrusion formed integral with one of the articular inserts 28. In this alternative embodiment, the protrusion extending from one of the articular inserts 28 would be at least partially disposed within the socket 120 defined by the opposing articular insert 28. A convex articular surface defined by the protrusion would cooperate with the concave articular surfaces 122 defined by the opposing socket 120 to provide pivotal and rotational articulating motion between the articular components 22a, 22b.

Additionally, although the devices and methods illustrated and described above are particularly useful in treating the lumbar region of the spine, it should nevertheless be understood that the present invention is also applicable to other portions of the spine, including the cervical or thoracic regions of the spine.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in

character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

WHAT IS CLAIMED IS:

1. An articular disc prosthesis for disposition between a first vertebra and a second vertebra, comprising:

5 a first articular component including a first bearing surface adapted to engage the first vertebra; and

a second articular component including second bearing surface adapted to engage the second vertebra, said first and second bearing surfaces defining a space therebetween; and

10 wherein at least one of said first and second articular components includes a concave articular surface that cooperates with a corresponding convex articular surface to provide articulating motion between the first and second articular components, at least a portion of said concave articular surface positioned beyond said space.

15 2. The articular disc prosthesis of claim 1, wherein each of said first and second articular components includes a concave articular surface that cooperates with said corresponding convex articular surface to provide said articulating motion, at least a portion of each of said concave articular surface positioned beyond said space.

20 3. The articular disc prosthesis of claim 2, further comprising an articular ball positioned between said first and second articular components, said articular ball cooperating with each of said concave articular surfaces to provide said articulating motion.

25 4. The articular disc prosthesis of claim 1, wherein said first and second bearing surfaces include means for gripping vertebral bone.

5. An articular disc prosthesis for replacement of a natural intervertebral disc, comprising:

30 a first articular component defining a first concave articular surface;
a second articular component defining a second concave articular surface; and
an articular ball positioned between said first and second concave articular surfaces to provide articulating motion between the first and second articular

components, said articular ball having a diameter greater than a height of the natural intervertebral disc.

5 6. An articular disc prosthesis for disposition between a first vertebra and a second vertebra, comprising:
 a first articular component adapted to engage the first vertebra; and
 a second articular component adapted to engage the second vertebra; and
 wherein each of said first and second articular components extends along an
10 axis and includes a central axial portion defining a convex lateral curvature and a pair of flanges extending laterally from said central axial portion in generally opposite directions.

15 7. The articular disc prosthesis of claim 6, wherein said central axial portion has a hemi-cylindrical shape.

 8. The articular disc prosthesis of claim 6, wherein each of said pair of flanges includes an outwardly facing bearing surfaces configured to engage a respective one of the first and second vertebrae.

20 9. The articular disc prosthesis of claim 8, wherein said outwardly facing bearing surfaces include means for gripping vertebral bone.

 10. The articular disc prosthesis of claim 6, wherein said pair of flanges of said first articular component defines a first pair of inwardly facing surfaces, said pair
25 of flanges of said second articular component defining a second pair of inwardly facing surfaces arranged generally opposite said first pair of inwardly facing surfaces, at least one of said first and second pairs of inwardly facing surfaces defining an outward taper.

30 11. The articular disc prosthesis of claim 10, wherein said outward taper extends in a lateral direction.

12. The articular disc prosthesis of claim 11, wherein said outward taper extends in an axial direction.

13. The articular disc prosthesis of claim 10, wherein each of said first and second pairs of inwardly facing surfaces defines an outward taper.

14. The articular disc prosthesis of claim 6, further comprising a spherical-shaped ball disposed between said first and second articular components to provide articulating motion therebetween, said spherical-shaped ball being at least partially positioned within said central axial portion of said first and second articular components.

15. The articular disc prosthesis of claim 6, wherein each of said first and second articular components includes a lip extending axially from said central axial portion, said lip including an outwardly facing bearing surface configured to engage a respective one of the first and second vertebrae.

16. The articular disc prosthesis of claim 15, wherein said lip includes an axially facing surface, said axially facing surface defining a recessed area extending inwardly toward said central axial portion.

17. An articular disc prosthesis for disposition between a first vertebra and a second vertebra, comprising:

a first modular articular component; and

a second modular articular component; and

wherein each of said first and second modular articular components includes:

an outer shell portion configured to engage a corresponding one of the first and second vertebrae; and

an inner insert portion removably engaged with the outer shell portion, said inner insert portion including an articular surface cooperating with a corresponding articular surface to provide articulating motion between said first and second modular articular components.

18. The articular disc prosthesis of claim 17, further comprising an articular ball positioned between said first and second modular articular components; and wherein said articular surface of each of said inner insert portions is a concave articular surface, said articular ball cooperating with said concave articular surfaces to provide said articulating motion.

19. The articular disc prosthesis of claim 18, wherein said inner insert portions are formed of a first material, said articular ball formed of a second material different from said first material.

20. The articular disc prosthesis of claim 19, wherein one of said first and second materials is a metallic material, and wherein the other of said first and second materials is a plastic material.

21. The articular disc prosthesis of claim 17, wherein said inner insert portion is slidably disposed within said outer shell portion and is securely engaged thereto by a number of fasteners.

22. A method of implanting an articular disc prosthesis between first and second vertebrae, comprising:

providing an articular disc prosthesis having a first articular component adapted to engage a first vertebra and a second articular component adapted to engage a second vertebra, each of the first and second articular components extending along an axis and including a central axial portion defining a convex lateral curvature and a pair of flanges extending laterally from the central axial portion in generally opposite directions;

removing at least a portion of a natural intervertebral disc from between the first and second vertebrae to form an intervertebral space;

forming an elongate recess along a central region of each of the first and second vertebrae; and

implanting the articular disc prosthesis within the intervertebral space by

inserting the central axial portions of the first and second articular components within the elongate recesses of the first and second vertebrae.

23. The method of claim 22, wherein the inserting comprises axially
5 displacing the central axial portions of the first and second articular components along the elongate recesses in the first and second vertebrae.

24. The method of claim 22, further comprising controlling the forming of
the elongate recesses to a predetermined depth.

10

25. The method of claim 24, wherein the central axial portions of the first
and second articular components have an axial length substantially equal to the
predetermined depth of the elongate recesses.

15 26. The method of claim 25, wherein the forming of the elongate recesses
comprises reaming.

27. The method of claim 22, further comprising engaging the pair of flanges
of each of the first and second articular components against the vertebral endplate of a
20 corresponding one of the first and second vertebrae.

28. The method of claim 22, wherein the central axial portion of the first and
second articular components and the elongate recesses formed in the first and second
vertebrae each have a hemi-cylindrical configuration.

25

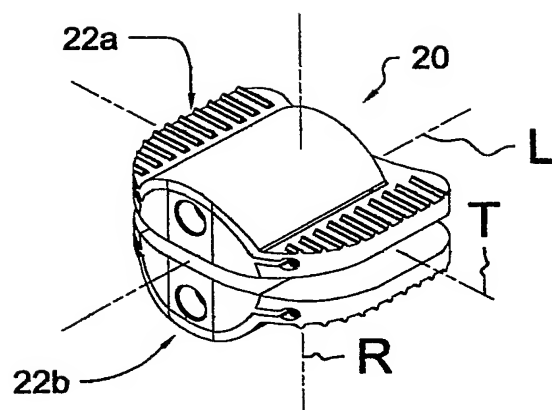


Fig. 1

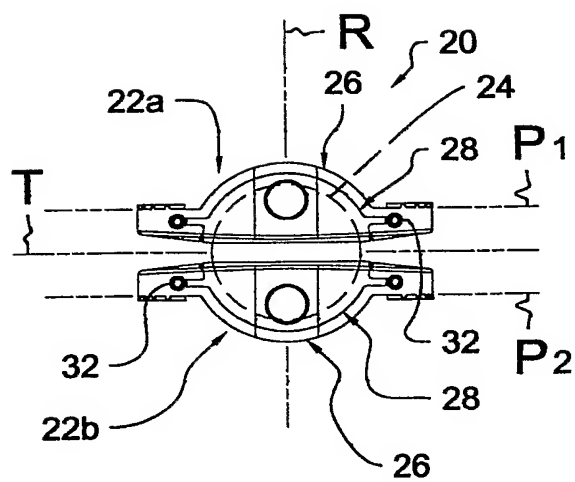


Fig. 2

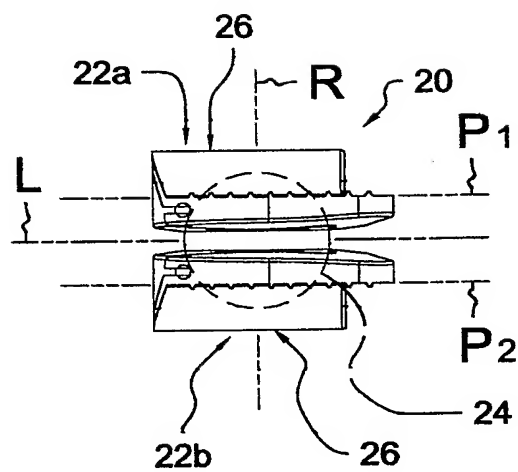


Fig. 3

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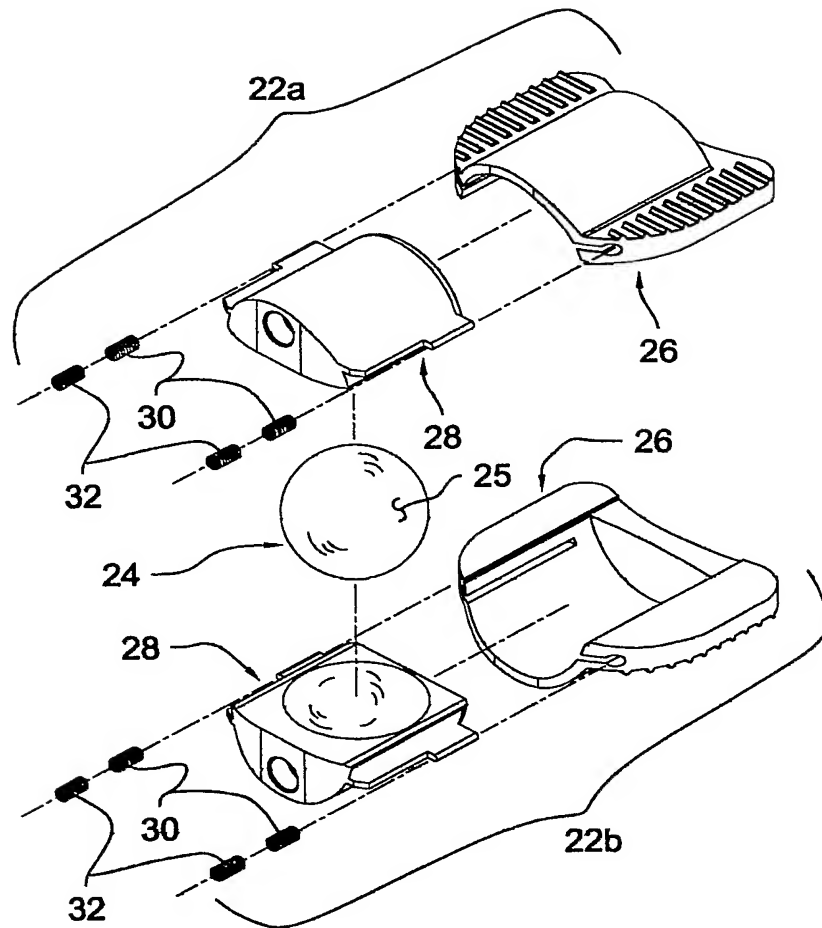


Fig. 4

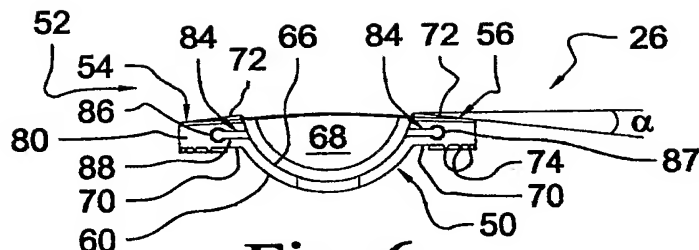


Fig. 6

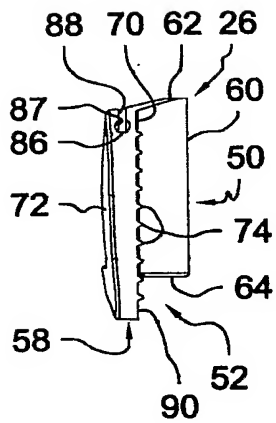


Fig. 7

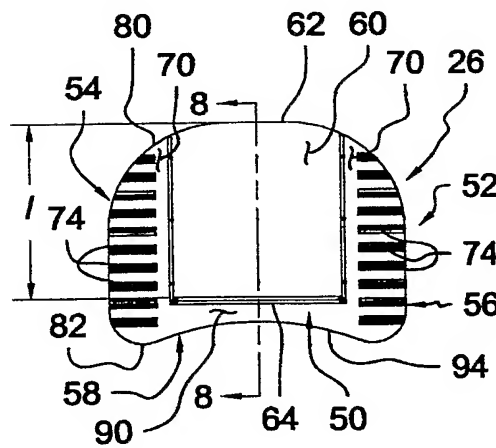


Fig. 5

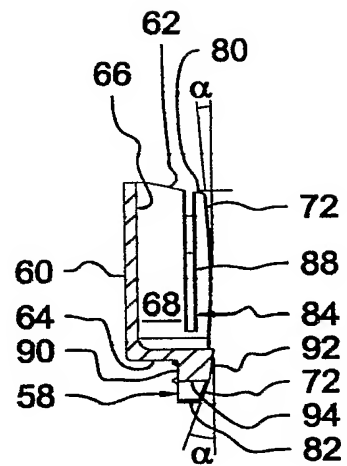


Fig. 8

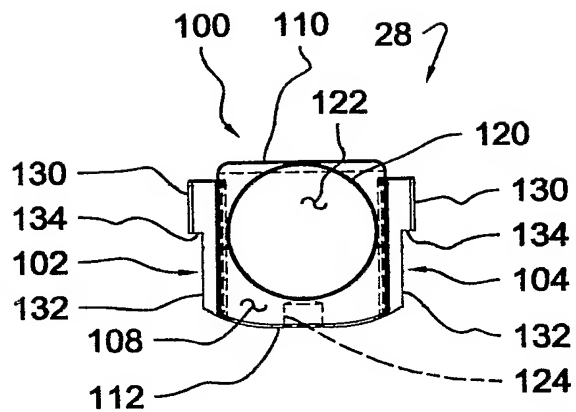


Fig. 10

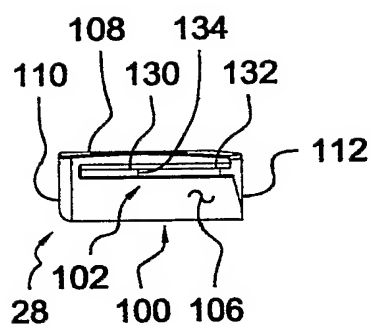


Fig. 11

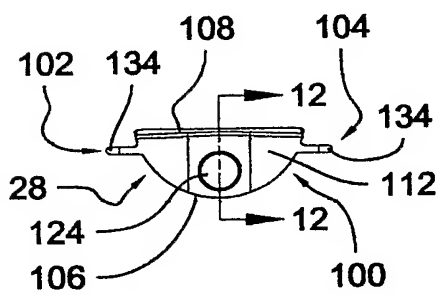


Fig. 9

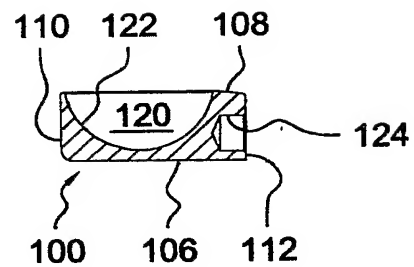


Fig. 12

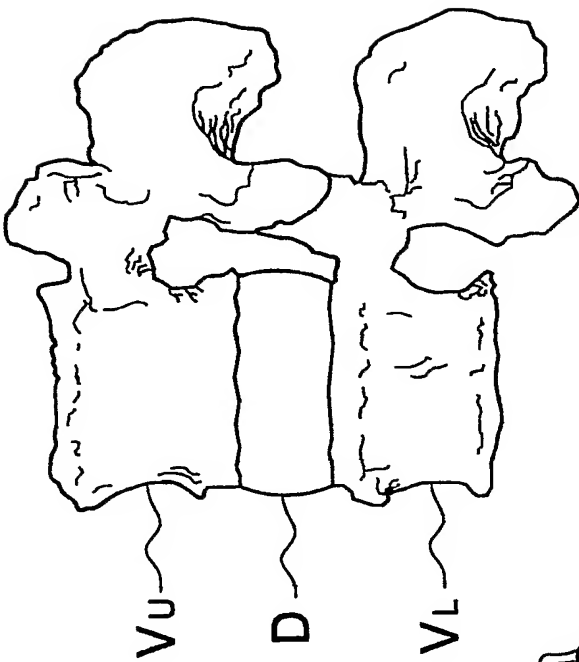


Fig. 13

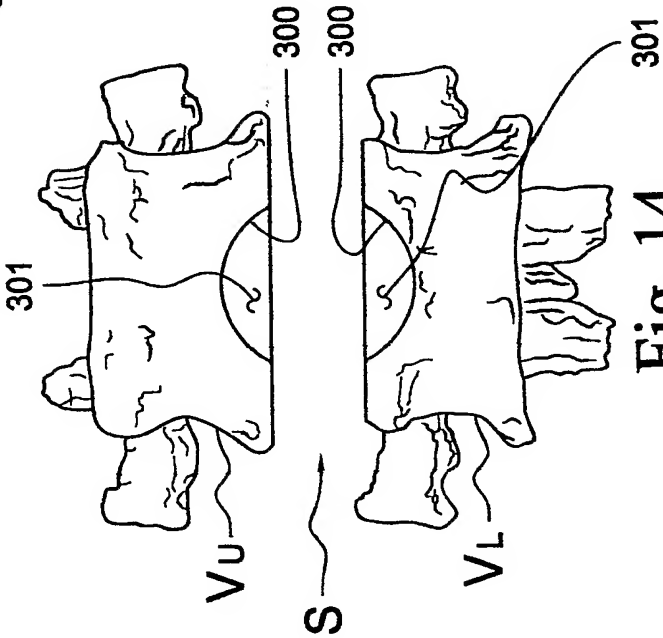


Fig. 14

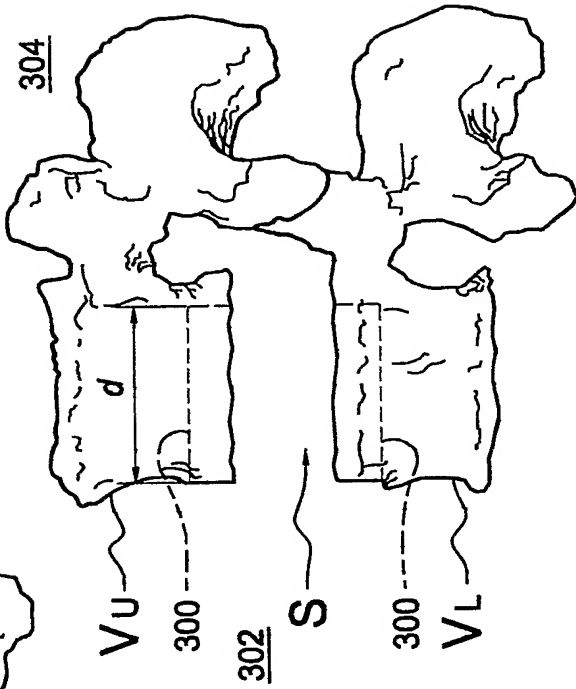


Fig. 15

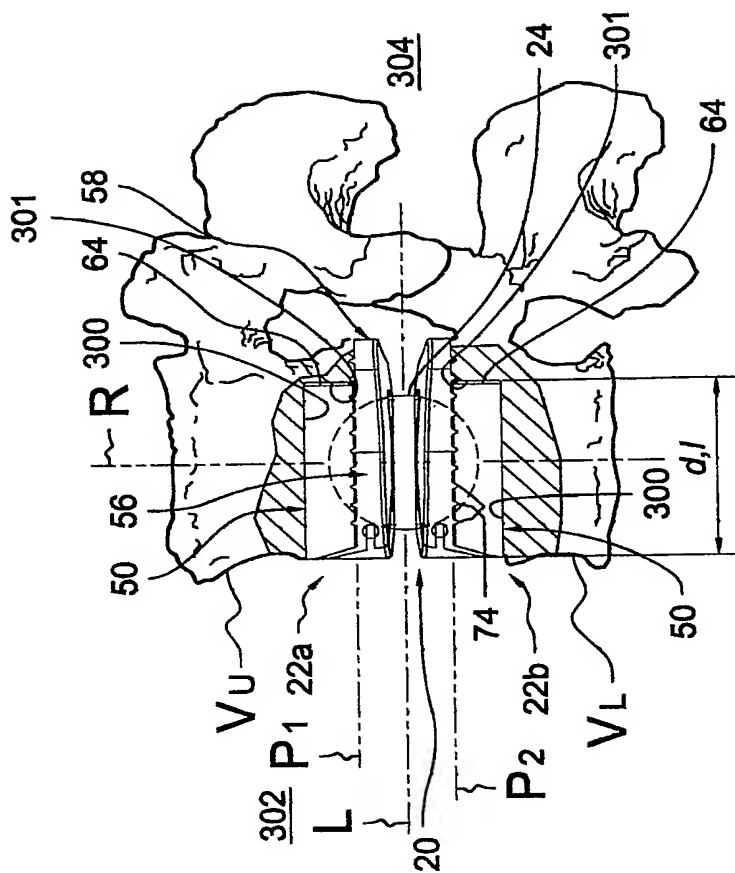


Fig. 16

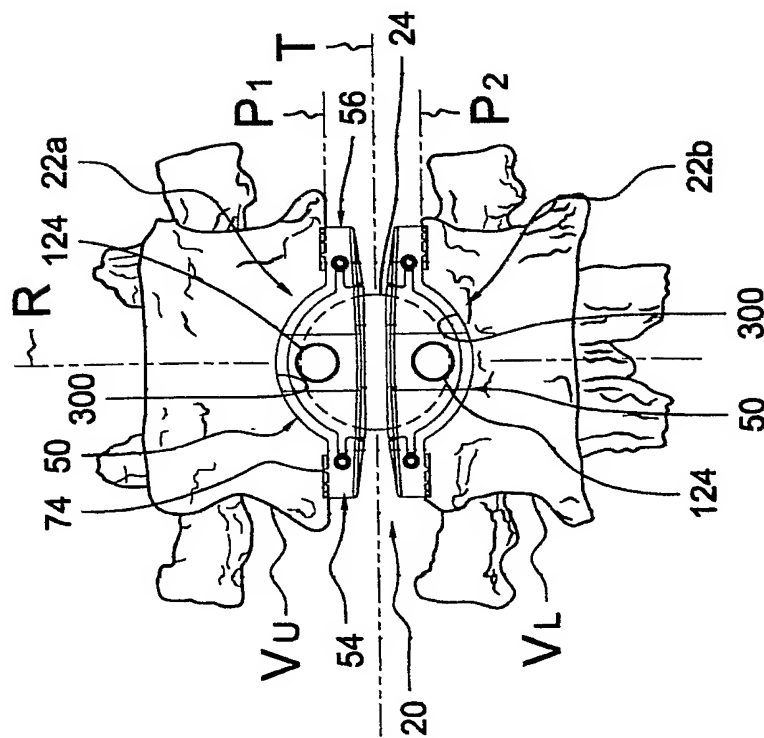


Fig. 17

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 03/12337

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	EP 0 955 021 A (LINK WALDEMAR GMBH CO) 10 November 1999 (1999-11-10) claim 1; figure 7 ---	1, 2, 4
X	FR 2 801 782 A (GRAF HENRY) 8 June 2001 (2001-06-08) figure 4 ---	1-3
X	WO 01 64140 A (BUHLER MARKUS ; RAMADAN AYMEN (CH); SCIENT X (FR)) 7 September 2001 (2001-09-07) abstract --- -/--	17

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

7 August 2003

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/12337

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	FR 2 805 985 A (EUROSURGICAL) 14 September 2001 (2001-09-14) claim 1 -----	1

INTERNATIONAL SEARCH REPORT

international application No.
PCT/US 03/12337

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 22-28
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/US 03/12337

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(19) World Intellectual Property Organization
International Bureau



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6 November 2003 (06.11.2003)

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(30) Priority Data:
60/374,747 23 April 2002 (23.04.2002) US
60/445,958 7 February 2003 (07.02.2003) US
60/449,642 24 February 2003 (24.02.2003) US
10/420,423 22 April 2003 (22.04.2003) US

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(74) Agent: **POSA, John, G.**; Gifford, Krass, Groh, Sprinkle, Anderson, & Citkowski, P.C., Suite 400, 280 N. Old Woodward Avenue, Birmingham, MI 48009 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

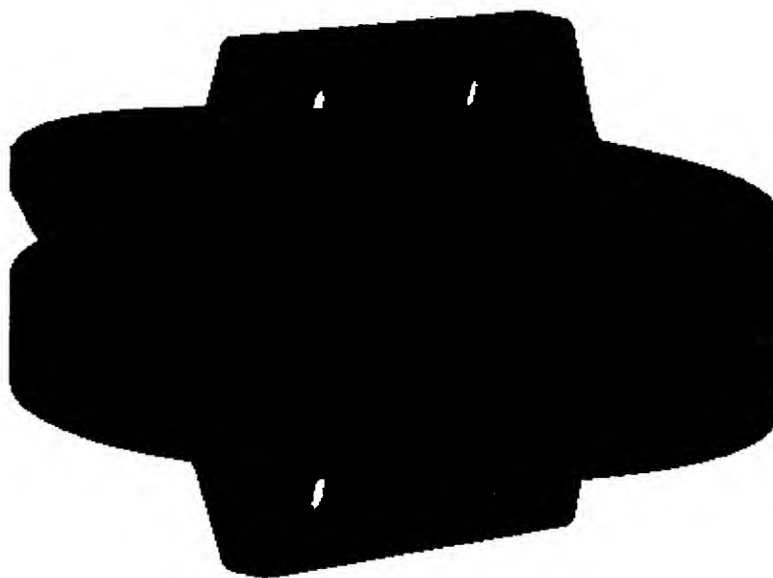
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ARTIFICIAL DISC REPLACEMENTS WITH NATURAL KINEMATICS



(57) **Abstract:** This invention improves upon prior art total disc replacements (TDRs) by more closely replicating the kinematics of a natural disc. The preferred embodiments feature two or more fixed centers of rotation (CORs) and an optional variable COR (VCOR) as the artificial disc replacement (ADR) translates from a fixed posterior COR that lies posterior to the COR of the TDR to facilitate normal disc motion. The use of two or more CORs allows more flexion and more extension than permitted by the facet joints and the artificial facet (AF). AF joint-like components may also be incorporated into the design to restrict excessive translation, rotation, and/or lateral bending.



WO 03/090649 A1

- 1 -

ARTIFICIAL DISC REPLACEMENTS WITH NATURAL KINEMATICS

REFERENCE TO RELATED APPLICATIONS

This application claims priority from U.S. Provisional Patent Application Serial Nos. 60/374,747, filed April 23, 2002; 60/445,958, filed February 7, 2003; and 60/449,642, filed February 24, 2003. The entire content of each application is
5 incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates generally to artificial disc replacements (ADRs) and, more particularly, to ADRs facilitating more natural kinematics.

BACKGROUND OF THE INVENTION

10 Many spinal conditions, including degenerative disc disease, can be treated by spinal fusion or through artificial disc replacement (ADR). ADR has several advantages over spinal fusion. The most important advantage of ADR is the preservation of spinal motion. Spinal fusion eliminates motion across the fused segments of the spine. Consequently, the discs adjacent to the fused level are
15 subjected to increased stress. The increased stress increases the changes of future surgery to treat the degeneration of the discs adjacent to the fusion. However, motion through an ADR also allows motion through the facet joints. Motion across arthritic facet joints could lead to pain following ADR. Some surgeons believe patients with degenerative disease and arthritis of the facet joints are not candidates for ADR.

20 Current ADR designs do not attempt to limit the pressure across the facet joints or facet joint motion. Indeed, prior art ADRs generally do not restrict motion. For example, some ADR designs place bags of hydrogel into the disc space which do not limit motion in any direction. In fact, ADRs of this kind may not, by themselves, provide sufficient distraction across the disc space. ADR designs with metal plates
25 and polyethylene spacers may restrict translation but they do not limit the other motions mentioned above. The articular surface of the poly spacer is generally convex in all directions. Some ADR designs limit motion translation by attaching the ADR halves at a hinge.

- 2 -

One of the most important features of an artificial disc replacement (ADR) is its ability to replicate the kinematics of a natural disc. ADRs that replicate the kinematics of a normal disc are less likely to transfer additional forces above and below the replaced disc. In addition, ADRs with natural kinematics are less likely to stress the facet joints and the annulus fibrosus (AF) at the level of the disc replacement. Replicating the movements of the natural disc also decreases the risk of separation of the ADR from the vertebrae above and below the ADR.

The kinematics of ADRs are governed by the range of motion (ROM), the location of the center of rotation (COR) and the presence (or absence) of a variable center of rotation (VCOR). Generally ROM is limited by the facet joints and the AF. A natural disc has a VCOR, that is, the COR varies as the spine bends forward (flexion) and backward (extension). Typically, the vertebra above a natural disc translates forward 1-2mm as the spine is flexed.

Prior art total disc replacements (TDR), that is, ADRs with rigid plates that attach to the vertebrae, do not replicate the kinematics of the natural disc. Generally, the COR lies too anterior. Most prior art TDRs also rely on a single, fixed COR. As a result, many of the prior art TDRs have a limited ROM.

SUMMARY OF THE INVENTION

This invention improves upon prior art TDRs by more closely replicating the kinematics of a natural disc. The preferred embodiments feature two or more fixed centers of rotation (CORs) and an optional variable COR (VCOR) as the ADR translates from a fixed posterior COR to a more anterior COR.

The multiple CORs permit a TDR with a posterior COR that lies posterior to the COR of the TDR to facilitate normal disc motion. The use of two or more CORs allow more flexion and more extension than permitted by the facet joints and the AF. Artificial facet joint-like components may also be incorporated into the design to restrict excessive translation, rotation, and/or lateral bending.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a sagittal cross section of a total disc replacement (TDR) according to the invention having three fixed centers of rotation (CORs);

- 3 -

FIGURE 2 is a sagittal cross section of the TDR of Figure 1 extended 5 degrees, more or less;

FIGURE 3 is a sagittal cross section of the TDR of Figure 1 showing various degrees of flexion;

5 FIGURE 4 is a sagittal cross section of another embodiment of a TDR having an anterior COR and a posterior COR;

FIGURE 5 is a sagittal cross section of the TDR of Figure 4 in a flexed position;

10 FIGURES 6A and 6B are drawings that show the articulating surfaces of the TDR drawn in Figure 4;

FIGURE 7 is a sagittal cross section of another embodiment having an anterior and a posterior COR;

FIGURE 8 is a sagittal cross section of the TDR of Figure 7 in a more flexed position;

15 FIGURE 9 is a view of the articulating surfaces of the TDR of Figure 7;

FIGURE 10 is an oblique view of the assembled TDR drawn in Figure 7;

FIGURE 11A is a view of the anterior side of a cervical embodiment of the TDR of Figure 7;

FIGURE 11B is a view of the lateral side of the TDR of Figure 11A;

20 FIGURE 11C is a view of the interior of the TDR drawn in Figure 11A;

FIGURE 12A is a sagittal cross section of yet a further embodiment of an artificial disc replacement according to the invention;

FIGURE 12B is a sagittal cross section of the embodiment of the ADR of Figure 12A;

25 FIGURE 12C is a view of the side of the ADR of Figure 12A;

FIGURE 13A is a view of the side of the ADR of Figure 12A including modular shims; and

FIGURE 13B is an exploded view of the embodiment of the ADR shown in Figure 13A.

30

DETAILED DESCRIPTION OF THE INVENTION

My U.S. Provisional Patent Application Serial No. 60/374,747, incorporated herein by reference, describes various improved artificial disc replacements (ADRs), including various embodiments that restrict spinal extension, rotation, translation, and/or lateral bending. In one disclosed configuration, rotation and translocation are limited by a "spoon-on-spoon" type of cooperation. Wedge or trapezoid-shaped ADRs are also presented to preserve lordosis. Fasteners may be used to fix the ADR to upper and lower vertebrae. An optional lip may additionally be provided to prevent the trapping of soft tissue during the movement from a flexion to neutral position.

The present invention extends such teachings through total disc replacements (TDRs) that more closely replicate the kinematics of a natural disc. The preferred embodiments feature two or more fixed centers of rotation (CORs) and an optional variable COR (VCOR) as the ADR translates from a fixed posterior COR to a more anterior COR. The multiple CORs permit a TDR with a posterior COR that lies posterior to the COR of the TDR to facilitate normal disc motion. The use of two or more CORs allow more flexion and more extension than permitted by the facet joints and the AF. Artificial facet joint-like components may also be incorporated into the design to restrict excessive translation, rotation, and/or lateral bending.

Figure 1 is a sagittal cross section of a TDR according to the invention having three fixed CORs. Articulation occurs at the posterior COR when the spine is in a neutral to extended position. Figure 2 is a sagittal cross section of the TDR drawn in Figure 1 with the ADR extended 5 degrees, more or less. Figure 3 is a sagittal cross section of the TDR drawn in Figure 1 in various degrees of flexion. As illustrated in the figure, the COR migrates anteriorly from a more posterior COR to a more anterior COR as the TDR is flexed.

Figure 4 is a sagittal cross section of another embodiment of the invention having an anterior COR and a posterior COR. In this case, the TDR articulates at the posterior COR with the TDR in neutral to extended position. Figure 5 is a sagittal cross section of the TDR drawn in Figure 4 in a flexed position. Note that the superior TDR endplate translates forward from the posterior COR to the anterior COR as the ADR moves from a neutral or extended position to a flexed position. Figures

- 5 -

6A and 6B are a view of the articulating surfaces of the TDR drawn in Figure 4. The inferior TDR endplate is shown in Figure 6A, and the inferior surface of the superior TDR endplate is shown in Figure 6B.

Figure 7 is a sagittal cross section of a further embodiment of the invention, including an anterior and a posterior COR. The design also includes novel artificial facet joint-like components that prevent excessive translation, rotation, or lateral bending. Figure 8 is a sagittal cross section of the TDR drawn in Figure 7 in a more flexed position. The drawing illustrates a gap between the artificial facet joint-like portions of the device. Figure 9 is a view of the articulating surfaces of the TDR drawn in Figure 7. The superior surface of the inferior TDR endplate is drawn on the left. Figure 10 is an oblique view of the assembled TDR drawn in Figure 7. This embodiment of the TDR illustrates the use of a toroidal patch and two spherical patches to form the anterior articulating surface of the lower plate. The novel torodial-spherical surface facilitates lateral bending.

Figure 11A is a view of the anterior side of a cervical embodiment of the TDR drawn in Figure 7. Screws can be inserted through the holes in the TDR to attach the TDR to the vertebrae. A reversible locking mechanism can be used to prevent the screws from backing out of the vertebrae. Figure 11B is a view of the lateral side of the TDR drawn in Figure 11A. Figure 11C is a view of the interior of the TDR drawn in Figure 11A. The superior surface of the inferior component of the TDR is drawn on the left.

Figure 12A is a sagittal cross section of another embodiment wherein, in contrast to the embodiment of Figure 7, the articulating surfaces of the anterior and/or the posterior CORs are not congruent. The use of non-congruent articulating surfaces uncouples translation from rotation. ADRs with non-congruent joint surfaces allow greater spinal flexion and extension without corresponding subluxation of the vertebrae. The spherical projections from the upper and lower ADR endplates can cooperate to prevent the upper ADR endplate from translating posteriorly over the inferior ADR endplate. The drawing illustrates the different radius of curvature of the components forming the joint in the posterior aspect of the ADR.

Figure 12B is a sagittal cross section of the embodiment of the ADR drawn in Figure 12A in a flexed position. The drawing illustrates the different radius of curvature of the components forming the joint in the anterior aspect of the ADR.

- 6 -

Figure 12C is a view of the side of the ADR drawn in Figure 12A. Artificial facet joint-like components, similar to those drawn in Figure 7, prevent excessive forward translation of the upper ADR endplate relative to the lower ADR endplate. The artificial facet joint-like components can also limit axial rotation and lateral bending.

5 Figure 13A is a view of the side of the ADR drawn in Figure 12A, with modular shims. Modular shims can be used to increase the lordosis, or wedge shape, of the ADR. The modular shims can be attached to the top of the superior ADR endplate and/or the bottom of the inferior ADR endplate. The shims could fasten to the keels of the ADR. Alternatively, the shims could attach to another part of the ADR
10 endplates. Lastly, the shims could simply lay on the ADR endplates. The shim inventory would include shims with different thickness and different angles. Figure 13B is an exploded view of the embodiment of the ADR drawn in 13 A.

Although surfaces depicted herein are shown as being 'congruent,' this is not necessary according to the invention. For example, a concave surface may have a
15 radius of curvature that is larger than the radius of curvature of an articulating convex surface such that the two surfaces are not in direct or intimate contact at all times. Both symmetrical and asymmetrical joints may also be used. A portion of the back of the posterior joint may be removed to move the posterior COR further posterior and to increase the surface area of the posterior joint by increasing the radius of the surface.
20 The articulating surface may be formed by a toroidal region and a spherical region, in this and other embodiments non-spherical surfaces may also be used to permit translation, rotation or other movements between more controlled articulations. TDRs according to the invention may be used in the cervical, thoracic, or lumbar spine.

ADR/TDRs according to this invention may also be composed of various
25 materials. For example, the components may be constructed of a metal such as chrome cobalt or a ceramic such as aluminum oxide. The novel TDR can also be made of a metal or ceramic coated with a harder or softer second material. That is, one or both of the components may be a metal coated with a ceramic, or a metal or ceramic coated with a diamond-like material or other hardened surface. Alternatively,
30 one or both of the components may be coated with a polymeric (i.e., polyethylene) surface or liner.

I claim:

- 7 -

1. An artificial disc replacement (ADR) configured for positioning
2 between vertebral bodies having an anterior portion and a posterior portion,
comprising:
 - 4 a superior component with a lower articulating surface; and
an inferior component with an upper articulating surface that cooperates with
6 the lower surface through one or more centers of rotation (CORs) located in the
anterior portion.
 2. The ADR of claim 1, wherein the lower articulating surface is convex
2 and the upper articulating surface is convex and the upper articulating surface is
concave.
 3. The ADR of claim 1, wherein the lower and upper articulating surfaces
2 are congruent or non-congruent.
 4. The ADR of claim 1, further including at least one set of articulating
2 surfaces forming a separate center of rotation in the posterior portion.
 5. The ADR of claim 4, wherein the anterior and posterior centers of
2 rotation are spherical, symmetrical, or both.
 6. The ADR of claim 4, wherein the anterior and posterior centers of
2 rotation are at different vertical heights.
 7. The ADR of claim 1, including at least one additional anterior or
2 posterior COR and a substantially smooth transition surface therebetween.
 8. The ADR of claim 1, further including one or more facet
2 approximating features that limit excessive translation, rotation and/or lateral bending.
 9. An artificial disc replacement (ADR) having two or more centers of
2 rotation (CORs) configured for positioning between vertebral bodies, each having an
anterior portion and a posterior portion, the ADR comprising:

- 8 -

- 4 a superior component with a lower articulating surface;
 an inferior component with an upper articulating surface; and
6 wherein one of the CORs is located between the posterior third and anterior
 two-thirds of the vertebral bodies.

10. The ADR of claim 9, wherein the lower articulating surface is convex
2 and the upper articulating surface is convex and the upper articulating surface is
 concave.

11. The ADR of claim 9, wherein the lower and upper articulating surfaces
2 are congruent or non-congruent.

12. The ADR of claim 9, further including at least one set of articulating
2 surfaces forming a separate center of rotation in the anterior portion.

13. The ADR of claim 12, wherein the anterior and posterior centers of
2 rotation are spherical, symmetrical, or both.

14. The ADR of claim 9, including at least one additional anterior or
2 posterior COR and a substantially smooth transition surface therebetween.

15. The ADR of claim 9, further including one or more facet
2 approximating features that limit excessive translation, rotation and/or lateral bending.

16. An artificial disc replacement (ADR) configured for positioning
2 between vertebral bodies having an anterior portion and a posterior portion,
 comprising:

- 4 a superior component with a lower articulating surface; and
 an inferior component with an upper articulating surface that cooperates with
6 the lower surface through two or more fixed or variable centers of rotation (CORs).

17. The ADR of claim 16, wherein the lower and upper articulating
2 surfaces are congruent or non-congruent.

- 9 -

18. The ADR of claim 16, wherein one of the CORs is located in the
2 anterior portion.

19. The ADR of claim 16, further including at least one set of articulating
2 surfaces forming a separate center of rotation in the posterior portion.

20. The ADR of claim 19, wherein the anterior and posterior centers of
2 rotation are spherical, symmetrical, or both.

21. The ADR of claim 19, wherein the anterior and posterior centers of
2 rotation are at different vertical heights.

22. The ADR of claim 16, including a substantially smooth transition
2 between the centers of rotation.

23. The ADR of claim 16, further including one or more facet
2 approximating features that limit excessive translation, rotation and/or lateral bending.

24. An artificial disc replacement (ADR) configured for positioning
2 between vertebral bodies, comprising:

a superior component with a lower articulating surface; and
4 an inferior component with an upper articulating surface that cooperates with
the lower surface through an anterior-to-posterior-oriented torodial region.

25. The ADR of claim 24, further including at least one spherical
2 articulating region adjacent the torodial region.

26. The ADR of claim 24, including a substantially smooth transition
2 between the torodial region and the spherical region.

27. The ADR of claim 24, wherein the lower and upper articulating
2 surfaces are congruent or non-congruent.

- 10 -

28. The ADR of claim 27, further including at least one set of articulating
2 surfaces forming a separate center of rotation in the posterior portion.

29. The ADR of claim 28, wherein the anterior and posterior centers of
2 rotation are spherical, symmetrical, or both.

30. The ADR of claim 24, further including one or more facet
2 approximating features that limit excessive translation, rotation and/or lateral bending.

Figure 1

neutral position

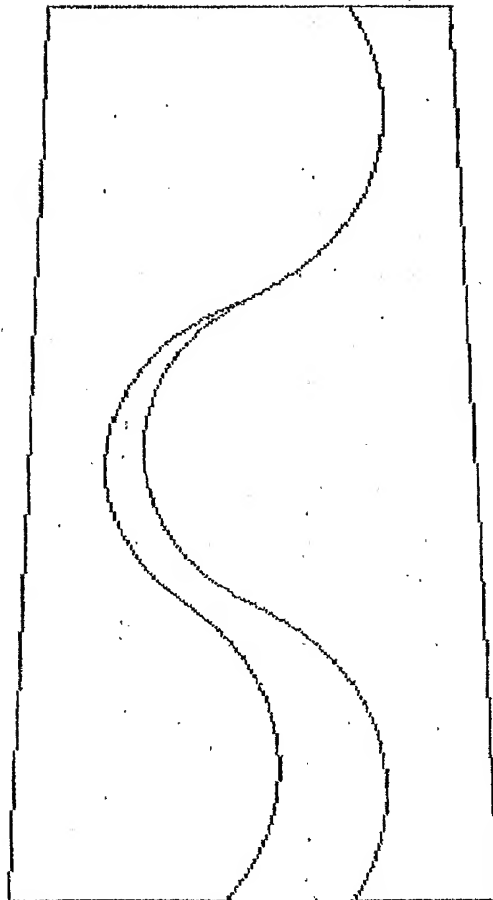


Figure 2

5 degree extension

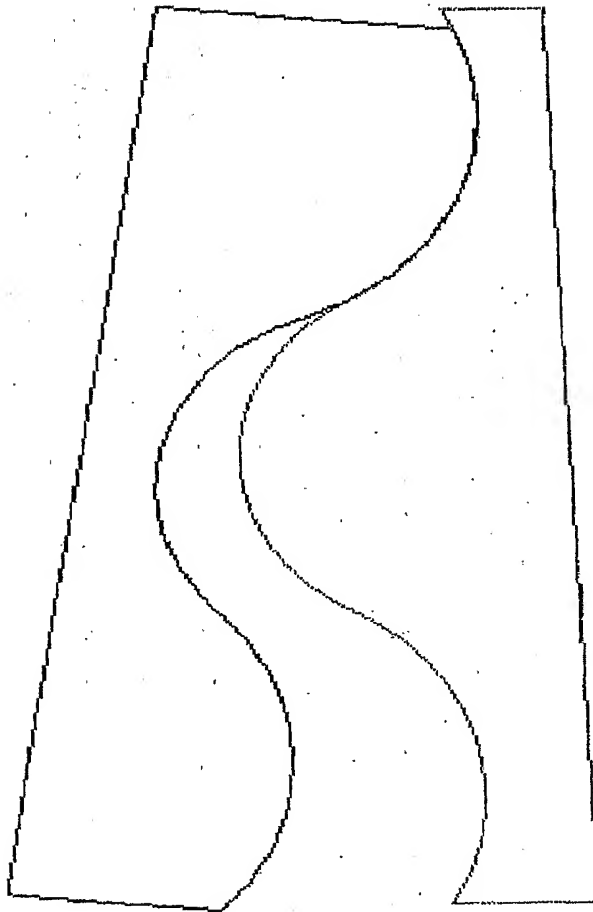


Figure 3

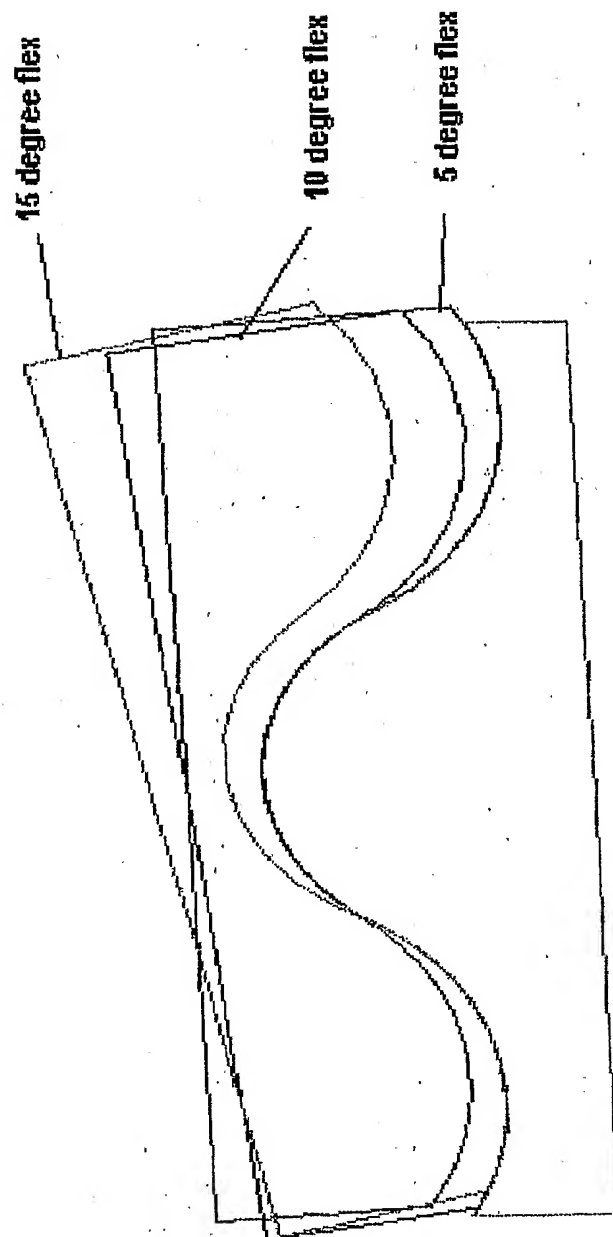


Figure 4

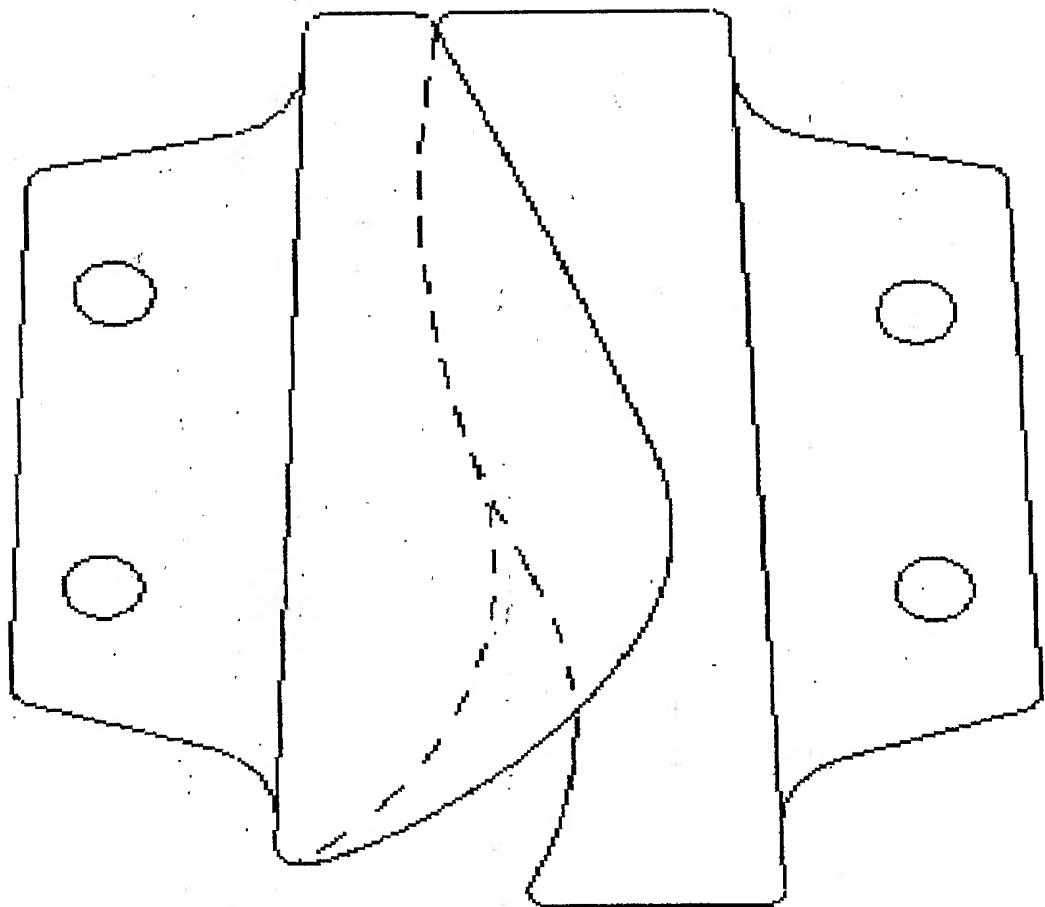
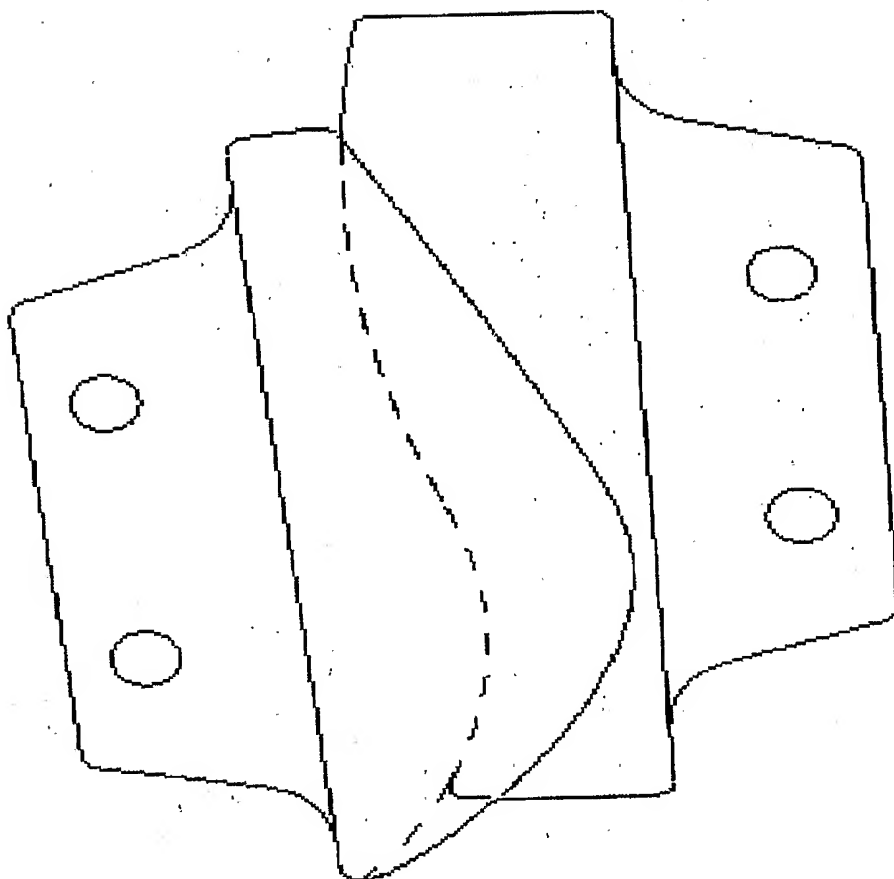


Figure 5

8 degrees flexion



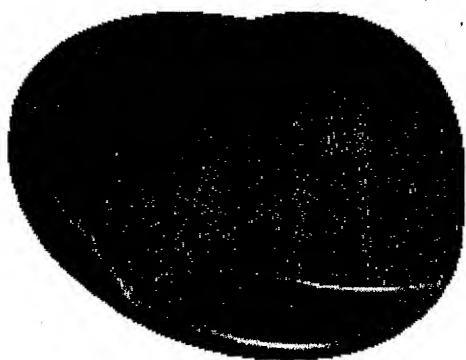


Fig-6A

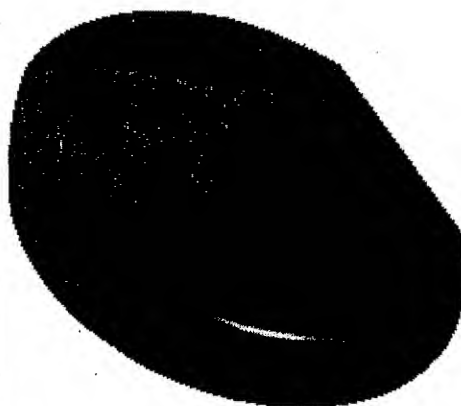


Fig-6B

Figure 7

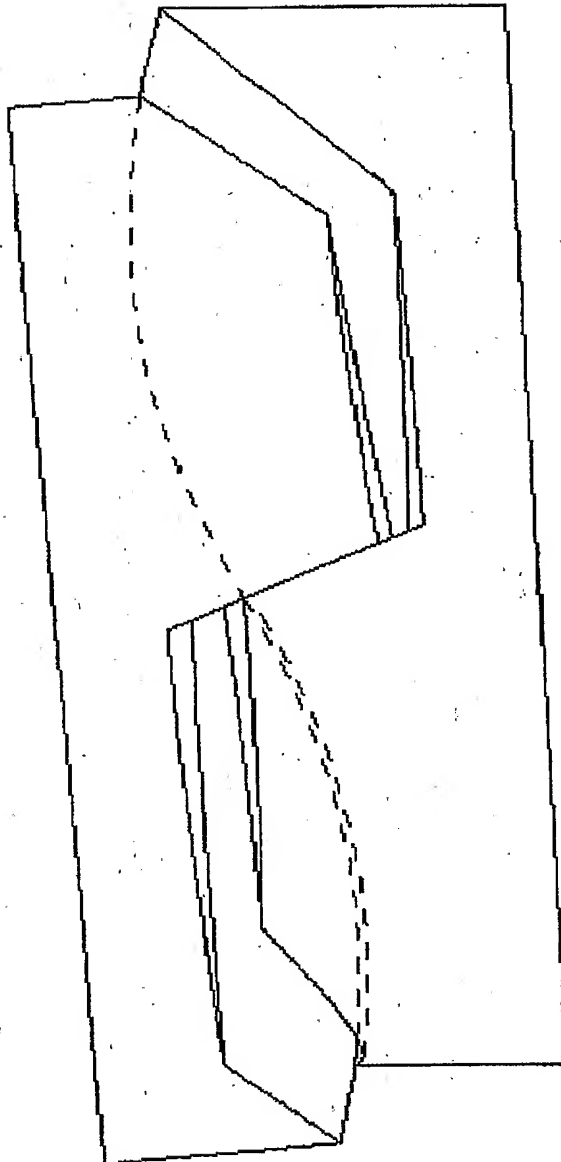
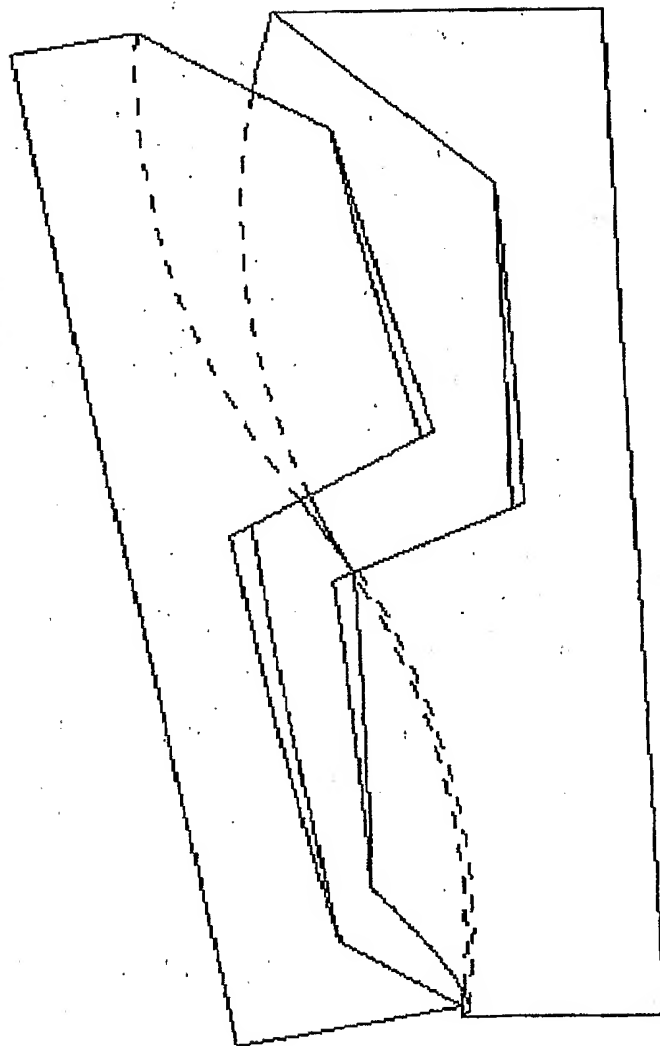


Figure 8



9 / 13

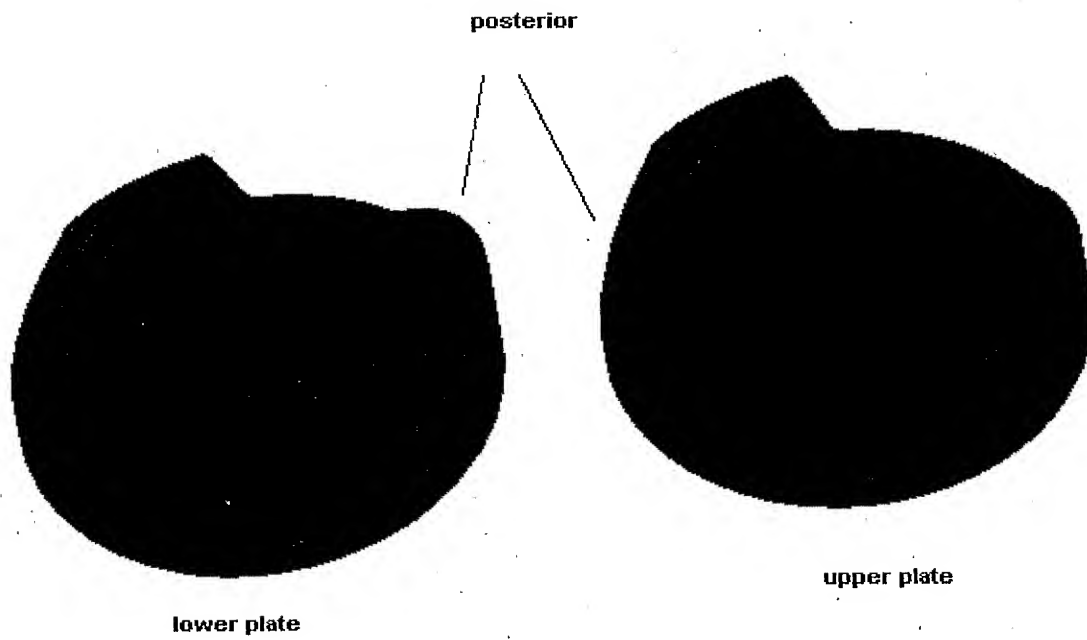


Fig - 9

10 / 13

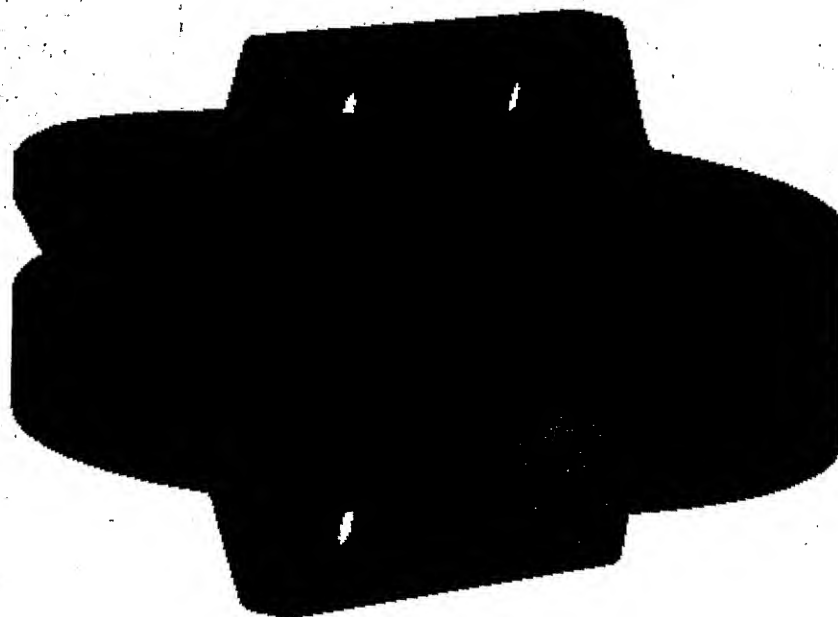
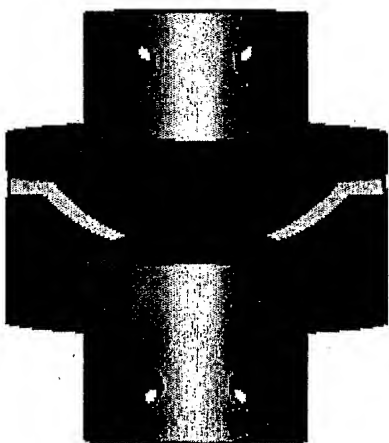


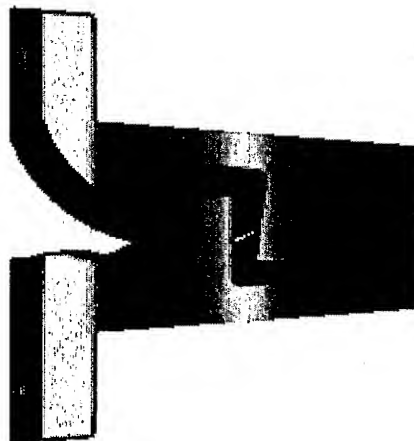
Fig- 10

11 / 13



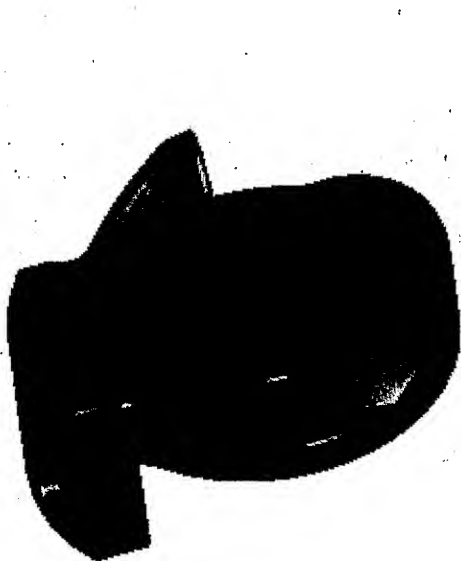
Anterior

Fig - 11A



Lateral

Fig - 11B



Interior Exposed

Fig - 11C

12/13

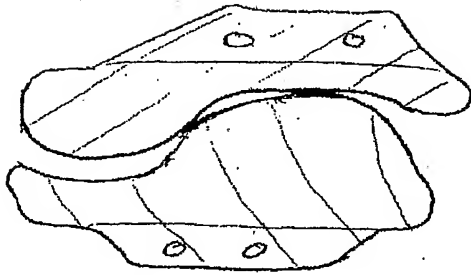


FIGURE 12 A

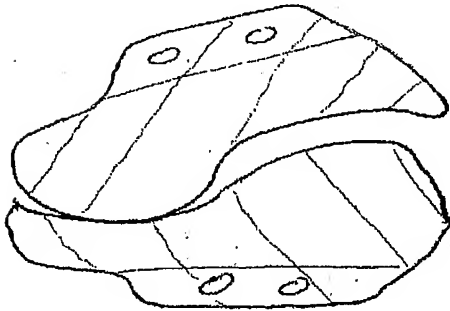


FIGURE 12 B

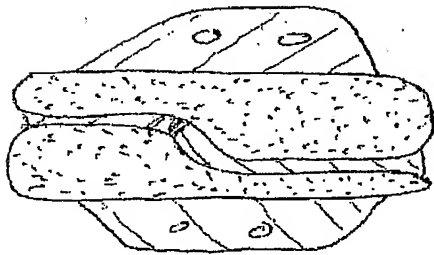


FIGURE 12 C

13 / 13

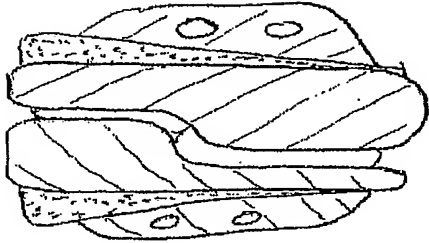


FIGURE 13A

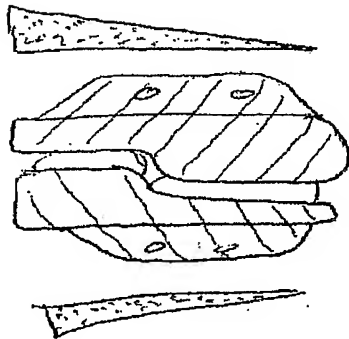


FIGURE 13B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/12500

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/44

US CL : 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.11, 17.14, 17.15, 17.16, 20.14, 20.22, 20.24; 606/61

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,039,763 A (SHELOKOV) 21 March 2000 (21.03.2000), Figures 3b and 4a and column 3, line 33 - column 4, line 12.	1-7, 9-14, and 16-22 ----- 15 and 23
X --- Y	US 6,146,421 A (GORDON et al) 14 November 2000 (14.11.2000), Figure 7c.	24-27 ----- 30
Y	US 5,401,269 A (BUTTNER-JANZ et al) 28 March 1995 (28.03.1995), Figures 8-15 and column 1, line 37 - column 2, line 28.	15, 23, and 30

☐

Further documents are listed in the continuation of Box C.

☐

See patent family annex.

* Special categories of cited documents:		"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

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10 July 2003 (10.07.2003)

Date of mailing of the international search report

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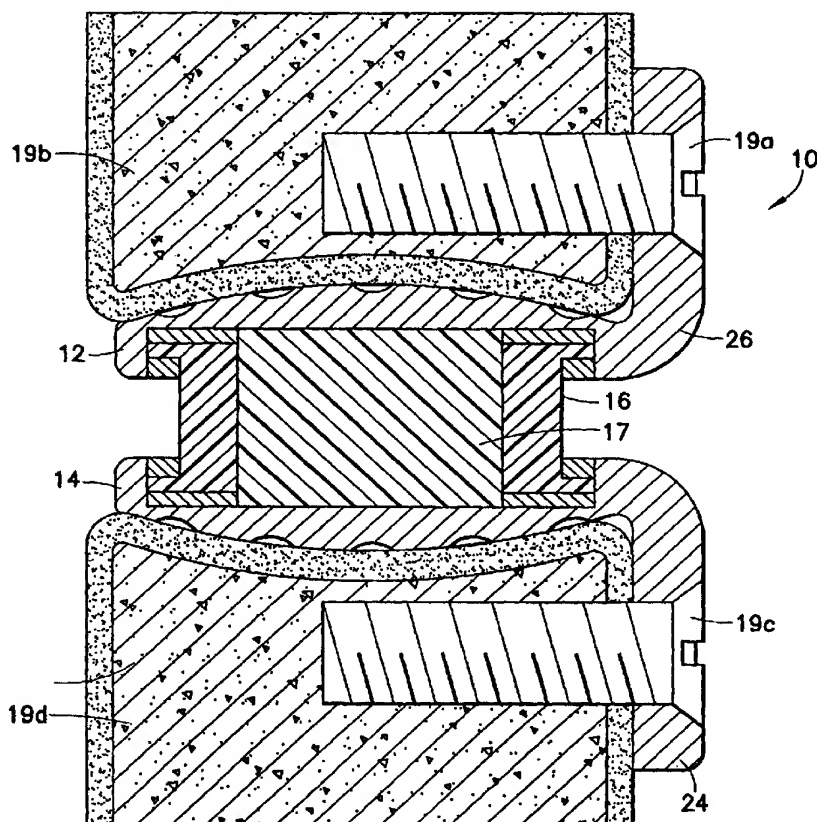
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[Continued on next page]

(54) Title: ARTIFICIAL INTERVERTEBRAL DISC



(57) Abstract: An artificial intervertebral disc assembly (10) according to an embodiment of the present invention is disclosed. Artificial intervertebral disc assembly (10) is comprised of a first anchor plate (12) and a second anchor plate (14), between which is disposed column (16). Column 16 (which is formed of ePTFE) includes therein column filler (17) (which is formed of an elastomer). Anchor plate (12) includes a mechanism (threaded fastener(19a)) for attachment to a vertebral body (19b). Likewise, anchor plate (14) includes a mechanism (threaded fastener(19c)) for attachment to a vertebral body (19d).



WO 03/090650 A1



SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

ARTIFICIAL INTERVERTEBRAL DISC

RELATED APPLICATIONS

This application claims the benefit under 35 U.S.C. 119(e) of U.S. Provisional Application Serial Number 60/375,842 filed April 25, 2002.

FIELD OF INVENTION

The present invention is directed to the field of prosthetic devices. More particularly, one embodiment of the present invention is directed to an artificial disc that can be used as a replacement for an intervertebral disc (e.g., a human intervertebral lumbar disc).

BACKGROUND OF THE INVENTION

As an alternative to spinal fusion techniques, numerous attempts have been made to design an artificial disc to replace an intervertebral lumbar disc that has become damaged or otherwise unhealthy. These devices have been reported to have attained varying degrees of success in performing functions of a healthy intervertebral disc and mimicking the behavior thereof (e.g., response to compressive forces applied to the spine and the preservation of proper kinematics of the spine).

SUMMARY OF THE INVENTION

The present invention provides an artificial intervertebral disc (AID) assembly. In one embodiment, the artificial disc assembly is comprised of first and second anchor plates, each of which has a vertebrae contacting side, and at least one column comprised of expanded poly(tetraflouroethylene) ("ePTFE") that is joined to the first and second anchor plates. The column may be a hollow column, or it may be a solid column. In yet another embodiment, the column may be filled with a compressible material, such as an elastomer. For example, the elastomer may be a silicone or a urethane or a thermoplastic elastomer. In yet another embodiment, the column may be solid ePTFE. In yet another embodiment of the present invention, the column of ePTFE may contain a compression element such as a spring constructed of a biocompatible material, such as titanium.

ePTFE is a well-known material processed from PTFE polymer. ePTFE has a network of nodes and fibrils that impart expandability, compressibility, and porosity (to name but a few of the properties possessed by ePTFE).

It is believed that the network of nodes and fibrils of an ePTFE structure, possibly combined with another spring-like material, presents very similar stress/strain behavior to that of a healthy, intervertebral disc (e.g., an intervertebral lumbar disc). That is, the amount of force per unit deflection needed to compress and/or elongate the ePTFE (e.g., in combination with another material) varies non-linearly (e.g., until the material is compressed to its solid height or the ePTFE is extended to full expansion of the nodes, at which point the modulus of elasticity increases still more rapidly, and the ePTFE stiffens). It is further believed that ePTFE allows for both compression and extension locally within the same structural member, which mimics the behavior of a disc (e.g., an intervertebral lumbar disc) in the modes of spinal extension, flexion, and lateral bending.

In yet another embodiment, the AID is constructed of first and second anchor plates, each of which has a vertebrae contacting side, and a plurality of columns of ePTFE that are joined to the first and second anchor plates. In one embodiment, two columns are joined to the anchor plates. In one embodiment, the columns may be filled with an elastic, compressible material, such as a silicone elastomer or urethane elastomer. In another embodiment, the column may be solid ePTFE.

In yet another embodiment, the prosthetic disc assembly is provided with anchor plates that have undercuts and/or tabs to facilitate the anchoring of the assembly to the vertebral bodies. The tabs may be provided with screw-holes into which bone screws can be inserted to anchor the assembly to the vertebral body. In yet another embodiment, the anchor plates may be assembled with the columns such that they are non-parallel (e.g., in order to provide a profile that substantially corresponds to the lordotic profile of the vertebral bodies). In another embodiment, the non-parallel angle may be 5° to 15°. In another embodiment, the final AID assembly may be provided with matching assemblies (e.g., a left and a right assembly), each assembly having first and second anchor plates and at least one column of ePTFE, that is joined to the anchor plates, the left and right assemblies being sized and dimensioned to reside adjacent to each other when positioned in the space between vertebral bodies.

In yet another embodiment, the AID is comprised of first and second anchor plates, each of which has a vertebrae contacting side, and at least one column comprised of ePTFE that is joined to the first and second anchor plates. Compression ferrules may join the column to the anchor plates. The ferrules may be fitted inside the column, and, as a result of the sizing of the ferrules relative to the sizing of the openings in the anchor plates, the ferrules impinge against the inner wall of the tube and force it outward against the walls of the anchor plates at their openings. As an alternative to joining the anchor plate to the columns with ferrules, the ends of the column may be flared and a compression flange affixed onto the anchor plate, trapping the ends of the column (once the column has been inserted through the anchor plates) in order to force the ends of the column axially into frictional engagement with the anchor plates.

In yet another embodiment, the assembly is comprised of first and second anchor plates and at least one column of ePTFE that is joined to the first and second anchor plates. The column may be chemically bonded to another element made, for example, from PTFE or ePTFE and then the column assembly may be captured by the anchor plate. As an alternative, the ePTFE may be heat-sealed or ultrasonically welded to another element made, for example, from PTFE or ePTFE and then the column assembly may be captured by the anchor plate. In another embodiment, the column may be impregnated with an elastomer such as urethane in order that the impregnated column can be bonded to another structure, thus allowing for termination to the anchor plate.

The materials used in constructing the implant may be biocompatible. The anchor plates, ferrules, compression flanges, and/or springs may be constructed of titanium 6AL4V ELI (extra low interstitial), a titanium alloy containing 6% aluminum and 4% vanadium. ePTFE, used to construct the columns, is a biocompatible material. Any additional elastomeric or non-elastomeric materials utilized in the assembly may be biocompatible.

It is contemplated that the artificial disc assembly of the present invention can be inserted with a posterior, lateral approach to the spine, as well as allowing for an anterior implantation approach.

In yet another embodiment, a thin coating of a silicone or urethane can be coated on the column of ePTFE to prohibit tissue growth on the column and within the interstices.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a cross sectional view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 2A shows a side elevation view along one side of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 2B shows a cross sectional view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 2C shows a side elevation view along another side of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 2D shows a perspective view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 2E shows a top plan view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 3A shows a side elevation view along one side of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 3B shows a side elevation view along another side of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 3C shows a perspective view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 3D shows a top plan view of an a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 4A shows a side elevation view along one side of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 4B shows a cross sectional view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 4C shows a side elevation view along another side of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 4D shows a perspective view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 4E shows a top plan view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 5A shows a side elevation view along one side of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 5B shows a cross sectional view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 5C shows a side elevation view along another side of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 5D shows a perspective view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 5E shows a top plan view of a component of an artificial intervertebral disc according to an embodiment of the present invention;

Figure 6 shows a side elevational view of another embodiment of the present invention in which the artificial intervertebral disc is comprised of a pair of implant components;

Figure 7 shows a cross sectional view of a component of an artificial intervertebral disc according to an embodiment of the present invention; and

Figure 8 shows a perspective view of another embodiment of the present invention in which the artificial intervertebral disc is comprised of a pair of implant components.

Among those benefits and improvements that have been disclosed, other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying figures. The figures constitute a part of this specification and include illustrative embodiments of the present invention and illustrate various objects and features thereof.

DETAILED DESCRIPTION OF THE INVENTION

Detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely illustrative of the invention that may be embodied in various forms. In addition, each of the examples given in connection with the various embodiments of the invention are intended to be illustrative, and not restrictive. Further, the figures are not necessarily to scale, some features may be exaggerated to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a representative basis for teaching one skilled in the art to variously employ the present invention.

As discussed above, the artificial intervertebral disc of the present invention may be comprised of one or more components or assemblies. In this regard, it is noted that each Figure (excluding Figures 6 and 8) show views of assemblies which may be combined (as shown in Figure 8, for example) to produce a final artificial intervertebral disc.

Referring now to Figure 1, an artificial intervertebral disc assembly according to an embodiment of the present invention is shown. As seen in this Figure, artificial intervertebral disc assembly 10 is comprised of a first anchor plate 12 and a second anchor plate 14, between which is disposed column 16. Column 16 (which is formed of ePTFE) includes therein column filler 17 (which is formed of an elastomer). Anchor plate 12 includes a mechanism (threaded fastener 19a) for attachment to a vertebral body 19b. Likewise, anchor plate 14 includes a mechanism (threaded fastener 19c) for attachment to a vertebral body 19d.

Referring now to Figures 2A-2E, an artificial intervertebral disc assembly according to another embodiment of the present invention is shown. As seen in these Figures, the artificial disc assembly 10 has a first anchor plate 12, a second anchor plate 14 (both of which may be constructed of titanium, for example), and columns 16, 18 which are constructed of ePTFE. The columns 16, 18 serve as spacer elements which keep the anchor plates 12, 14 apart from each other. As shown in Figure 2D, for example, the end surface 32 of columns 16, 18 terminate flush at the top surface 34 of anchor plate 12 (as well as flush at the bottom surface of anchor plate 14, which

configuration is not shown in this view). The outer diameter of the column lies against the inner diameter of the opening in the anchor plate. A compression ferrule 20, 22 is placed within the column at an end thereof, as shown in Figure 2B. The ferrule is sized to form a snug fit between the ferrule, column, and sidewalls defining the opening of the anchor plate. This forms a firm frictional engagement between the components that locks the columns in place.

In another embodiment, the ends of the columns may be flared and a compression flange affixed onto the anchor plate, trapping the ends of the column (once the column has been inserted through the anchor plates) in order to force the ends of the column axially into frictional engagement with the anchor plates.

In yet another embodiment shown in Figure 7, the ends of the column 16a are flared after extending through the thickness of the anchor plate such that the outer wall of the column lies against the top surface of the anchor plate 12 and the inner wall of the column faces outward axially. A compression flange 21 is affixed to the top surface of the anchor plate, forming a snug fit between the flange, column, and upper surface of the anchor plate. The flange 21 may be joined to the anchor plate 12 by securing a screw through bores provided in the flange and the anchor plate, or by another suitable arrangement, such as by passing a bolt through bores provided in the flange and the anchor plate and securing the bolt with a washer. When the flange is affixed in this manner, a firm frictional engagement is formed between these components, which locks the columns in place. An identical method of termination may be implemented at the opposite end of the column and bottom surface of anchor plate 14. In order to flare the end of the column, a slit may be provided at the end of the column, which could facilitate its flaring.

In one embodiment the column is constructed of ePTFE. ePTFE is an expanded PTFE that, as a result of the expansion process, possesses a network of nodes (pores), connected by fibrils, that impart certain mechanical properties to the material. For example, it is believed that the amount of force needed to compress the column may remain nearly constant over a given distance, until all of the voids between the nodes and fibrils are nearly compressed. At this point, it is further believed that near the solid height of the ePTFE, the compressive force may increase non-linearly with respect to the axial

deflection of the column such that the effective modulus of elasticity of the structure is increasing. Similar behavior may be seen when the column is decompressed in tension. It is believed that when the artificial disc assembly is inserted between vertebral bodies and subjected to customary loads, the artificial disc of this embodiment may perform similar to the way in which a healthy intervertebral lumbar disc will perform.

ePTFE is described in U.S. Patent No. 3,953,566 as follows “in the case of uniaxial expansion the nodes are elongated, the longer axis of a node being oriented perpendicular to the direction of expansion. The fibrils which interconnect the nodes are oriented parallel to the direction of expansion. These fibrils appear to be characteristically wide and thin in cross-section, the maximum width being equal to about 0.1 micron (1000 angstroms) which is the diameter of the crystalline particles. The minimum width may be 1 or 2 molecular diameters or in the range of 5 or 10 angstroms. The nodes may vary in size from about 400 microns to less than a micron, depending on the conditions used in the expansion. Products which have been expanded at high temperatures and high rates have a more homogeneous structure, i.e. they have smaller, more closely spaced nodes and these nodes are interconnected with a greater number of fibrils. These products are also found to have much greater strength.” This patent is incorporated herein by reference.

Referring once again to Figures 2A-2E, it is seen that in this embodiment there exists a portion 30, 31 of the anchor plate which is elevated beyond the surface, which elevated portion contacts the surface of the vertebral endplate. This elevated portion of the anchor plate may be the interface between the anchor plate and the vertebral body. The elevated interface may reside in a corresponding depression or groove formed in the vertebral endplate. The elevated interface may be furnished with an undercut 35, 36 to provide a dovetail fit between the anchor plate and the depression or groove that is formed in the vertebral body. This arrangement may facilitate the initial fixation of the AID device, by allowing the assembly to slide into place, or for ultimate fixation, by allowing bone to grow into the undercut region of the interface feature on the anchor plate. In one embodiment, the undercut 35, 36 may run linearly down the sides of the elevated portion, as in Figures 2A-2E. In yet another embodiment, the undercut 35, 36 may run down the center of the plate, as shown in Figures 4A-4E, in a configuration,

which in its cross section (see Figure 4C) resembles a light bulb, with a neck portion and a bulbous portion. In yet another embodiment, the undercut 35,36 may pass around the perimeter of the opening in the anchor plate, such as the daisy wheel configuration of Figures 3A-3D, or intersect linearly with a truncated daisy wheel configuration as in Figures 5A-5E.

The elevated interface may be provided on the anchor plate in order to form an interface between the vertebral bodies and the surface of the anchor plates. That is, over a period of time, the vertebral bodies may grow around the interface on each of the anchor plates, forming a complementary arrangement, which anchors the implant in place.

The artificial disc may be designed such that in addition to allowing for anterior implantation, it may be implanted posteriorly (i.e., the surgeon can implant the assembly from the backside of the patient).

In this regard it is noted that during the surgical procedure, the surgeon may make the requisite incisions or access the site where the unhealthy or damaged disc is to be removed. After removal of the unhealthy or damaged disc, the surgeon may cut grooves in the endplates of the vertebral bodies that were adjacent to the removed disc. The grooves that are cut may be sized and shaped to correspond to the interface on the elevated portion of the anchor plate.

The compressibility of the implant of the present invention may prove helpful during the implanting procedure. As the implant is being inserted between the vertebrae, the implant may be compressed to smaller proportions than its uncompressed height. The surgeon can then, prior to releasing the implant from its compressed height, adjust its position to insure that the elevated interface on the anchor plates and the grooves cut into the vertebral bodies are aligned with each other. After the surgeon has ensured this is the case, the implant may be released from its compressed state, so that the elevated interface enters the grooves.

Alternatively, the grooves may be cut in the vertebral body with a matching undercut, such that the anchor plates may be inserted from the side in a dovetail configuration. This embodiment may allow for positive initial tensile attachment between the anchor plates and the endplates, without having to wait for bony ingrowth.

Referring once again to attachment of the column(s) to the anchor plate(s), it is noted that techniques other than (or in addition to) those described above may be employed. For example, an intermediate design element may be employed whereby the intermediate design element may be joined to the column by, for example, ultrasonic welding, heat sealing (i.e., fusion welding) and/or chemical bonding (thus forming a column assembly). The intermediate design element may be constructed of ePTFE, PTFE, or another chemically compatible material. Once the column assembly has been formed, it may be attached to the anchor plate such that there exists a structurally sound connection.

In one embodiment, the ePTFE column is a hollow column. In another embodiment the column is filled with an elastomeric material, such as silicone or urethane.

In yet another embodiment, the ePTFE column contains a spring element, such as a titanium spring.

Of note, the physical properties exhibited by the columns may be modified by changing the physical dimensions of the cross section of the column, and/or by varying the density of the nodes of the ePTFE. This may alter the static, dynamic, and or kinematic behavior of the material.

In another embodiment the columns of ePTFE may be coated with a silicone or other biocompatible elastomer layer. Such a coating layer may prohibit the growth of tissue and/or bone within the interstices of the nodes, between the fibrils in the column. In another embodiment the elastomer may be extruded onto the column.

As shown in the Figures, the anchor plates may be disposed in a non-parallel configuration (in order to account for the lordotic angle of the vertebrae, for example). This will help insure that the surface of the anchor plate will contact a respective surface of the vertebral bodies to the fullest possible extent. An AID constructed in this manner may exhibit behavior similar to that of the original disc, which also reflected the lordotic angle between vertebral bodies. In one specific example, the angle may lie in the range of 5° to 15°, which should cover the lordotic angles of the vertebral bodies of most of the population.

In another embodiment the anchor plates may be constructed of a strong durable material that is biocompatible. A material which has gained widespread acceptance in constructing in vivo implants is titanium 6AL 4V ELI (extra low interstitial), an alloy containing 6% aluminum and 4% vanadium. One of ordinary skill in the art would readily appreciate the other materials that could be used to construct implants according to the present invention.

Referring now to Figures 2E and 5E, for example, it can be seen that anchor plate edges 38 and 39 may form angle θ . This angle may be provided to account for the angle at which the device enters the body. That is, the angle may be provided as a design feature in order to facilitate installation by particular approach, such as a posterior lateral approach, for example. Thus, the device may be designed to have a preselected angle θ that facilitates a particular approach to installation.

Figure 6 shows another embodiment of the present invention in which the artificial intervertebral disc is comprised of a pair of implant components (or assemblies) 10a, 10b. Each component (or assembly) 10a, 10b is provided with anchor plates 12a, 14a, 12b, 14b, and columns 16, 18, joined to the anchor plates in the manners previously discussed. The implant components (or assemblies) may be provided with matching lordotic profiles and may be intended to sit laterally adjacent to each other. This arrangement may provide flexibility in the insertion process, allowing one component to be inserted from each side of the spinal cord, for example.

Figure 8 shows another embodiment of the present invention in which the implant is comprised of a pair of implant components (or assemblies) 10a, 10b. Each component (or assembly) 10a, 10b is provided with anchor plates 12a, 14a, 12b, 14b, and columns 16a, 18a, 16b, 18b joined to the anchor plates in the manners previously discussed. The implant components (or assemblies) may be provided with matching lordotic profiles and may be intended to sit laterally adjacent to each other. This arrangement may provide flexibility in the insertion process, allowing one component to be inserted from each side of the spinal cord, for example. Of note, this Figure 8 shows an embodiment comprised of one component (or assembly) similar to the one shown in the views of Figures 5A-5E and another component (or assembly) also similar to the one shown in the views of Figures 5A-5E, but with an essentially mirror-image configuration

(multi-component (or multi-assembly) implants corresponding to embodiments shown in the other Figures are, of course, also contemplated by the present invention).

Turning now to Figures 1 to 8, the perimeters of the anchor plates may be provided with tabs 24, 26 that extend at an angle substantially normal to the plane of the anchor plates. The tabs 24, 26 have an outer surface and an inner surface that faces in toward the anchor plates. The tabs 24 may aid in attaining the correct positioning of the implant relative to the vertebral bodies it is positioned between. The correct position may be attained when the inner surface of the tabs 24, 26 lie substantially flush against the outer surface of the vertebral bodies. Optionally, the tabs 24, 26 may be provided with through bores, through which fixation devices, such as bone screws, may be inserted in order to lock the implant in place.

In yet another embodiment, the column of ePTFE may be a solid chord of material. In another embodiment, the ePTFE may be provided with non-expanded regions, such as at the anchoring regions, for example

In a further embodiment, the columns of ePTFE could be extruded to have greater wall thickness on one side or end as opposed to another side or end. For example, the walls of the anterior tube side may be extruded thicker than the walls of the posterior tube side.

In yet another embodiment, the device may be shaped as desired, such as having an oval shape or a kidney shape, for example. This could be effected by providing a desired shape to the anchor plates and/or the column(s).

The structural features of the invention, and methods for installing them, and for stabilizing the device, have been described. Of note, the implants of the present invention may provide one or more of the following attributes when inserted in the body (e.g., between vertebrae):

- Essentially the same articulation as a healthy intervertebral disc (e.g., intervertebral lumbar disc) may be realized;
- Essentially the same kinematic behavior as a healthy intervertebral disc (e.g., intervertebral lumbar disc) may be realized;
- Essentially the same dynamic behavior as a healthy intervertebral disc (e.g., intervertebral lumbar disc) may be realized;

- The static properties of the implant and a healthy intervertebral disc (e.g., intervertebral lumbar disc) may be substantially identical;
- The implant may be biocompatible;
- The device may be implanted by posterior or anterior approaches;
- The device may install in a relatively short period of time (e.g., around 90 minutes);
- The device may exhibit positive results in fatigue tests (i.e., the device may be usable after 10×10^6 cycles);
- The device may survive static loading, shear loading and testing to induce expulsion;
- The device may fixate rapidly to vertebral bodies;
- The device may minimize contact stress with vertebral bodies at the device interface; and
- The device may be auto-clavable.

While a number of embodiments of the present invention have been described, it is understood that these embodiments are illustrative only, and not restrictive, and that many modifications may become apparent to those of ordinary skill in the art.

What is claimed is:

1. An artificial intervertebral disc, comprising:
a first anchor member;
a second anchor member; and
a composite structure disposed between the first anchor member and the second anchor member, which composite structure is comprised of a column formed of ePTFE and a column filler formed of an elastomer.
2. The artificial intervertebral disc of claim 1, wherein the composite structure is configured such that the composite structure has associated therewith, in at least one axis, a load versus deflection behavior substantially similar to that of a substantially healthy human intervertebral disc.
3. The artificial intervertebral disc of claim 2, wherein the load versus deflection behavior is selected from the group of: (a) dynamic behavior, which dynamic behavior is a function of a time rate application of load; (b) kinematic behavior; and (c) static behavior.
4. The artificial intervertebral disc of claim 2, wherein the load versus deflection behavior includes a non-linear relationship between an amount of force required to compress the composite structure and a deflection of the composite structure.
5. The artificial intervertebral disc of claim 4, wherein a stiffness of the composite structure increases as the composite structure is compressed.
6. The artificial intervertebral disc of claim 2, wherein the column has a hole therethrough.
7. The artificial intervertebral disc of claim 6, wherein at least one of the column and the hole in the column has a substantially circular cross-section.

8. The artificial intervertebral disc of claim 7, wherein each of the column and the hole in the column has a substantially circular cross-section.

9. The artificial intervertebral disc of claim 8, wherein the column filler is disposed within the hole in the column.

10. The artificial intervertebral disc of claim 9, wherein the elastomer is selected from the group including: (a) a silicone; (b) a urethane; and (c) a thermoplastic elastomer

11. The artificial intervertebral disc of claim 6, wherein the composite structure is attached to at least one of the first member and the second member.

12. The artificial intervertebral disc of claim 11, wherein the composite structure is attached by a mechanism selected from the group of:

(a) compressing a portion of the column radially between a compression ferrule fitted in the hole in the column and a first mating surface of one of the first member and the second member, which first mating surface is formed by a hole through one of the first member and the second member; and

(b) flaring an end of the column and compressing the flared portion of the column between a capturing component and a second mating surface of one of the first member and the second member.

13. The artificial intervertebral disc of claim 12, wherein the column is inserted through the hole in one of the first member and the second member before the end of the column is flared.

14. The artificial intervertebral disc of claim 12, wherein the capturing component is attached to one of the first member and the second member by a mechanism selected from the group of:

(a) a mechanism for threading the capturing component to one of the first member and the second member;

(b) a mechanism for adhesively bonding the capturing component to one of the first member and the second member

(c) a mechanism for press-fitting the capturing component to one of the first member and the second member; and

(d) a mechanism for affixing the capturing component to one of the first member and the second member via at least one threaded fastener.

15. The artificial intervertebral disc of claim 6, wherein the column has a first end and a second end and at least one end of the column is attached to a flange by a mechanism selected from the group of: (a) fusion welding; (b) chemical bonding; and (c) ultrasonic welding.

16. The artificial intervertebral disc of claim 15, wherein the column is treated with a material which aids in the attachment to the flange, which treatment is selected from the group of: (a) impregnating the column with the material; and (b) coating the column with the material.

17. The artificial intervertebral disc of claim 15, wherein the flange is attached to at least one of the first member and the second member by a mechanism selected from the group of:

(a) capture behind a press-fit capture ring;

(b) threading the flange onto at least one of the first member and the second member; and

(c) attaching the flange to at least one of the first member and the second member via at least one threaded fastener.

18. The artificial intervertebral disc of claim 1, wherein the column is impregnated with a material that aids in preventing at least one of: (a) biological ingrowth into the column; and (b) biological attachment to the column.

19. The artificial intervertebral disc of claim 1, wherein the column is coated with a material that aids in preventing at least one of: (a) biological ingrowth into the column; and (b) biological attachment to the column.

20. The artificial intervertebral disc of claim 1, wherein the artificial intervertebral disc is configured to be implanted by at least one method selected from the group of: (a) posterior implantation; and (b) anterior implantation.

21. An artificial intervertebral disc, comprising:
a first anchor member;
a second anchor member; and
at least two composite structures disposed between the first anchor member and the second anchor member, wherein a first one of the composite structures is comprised of a first column formed of ePTFE and a first column filler formed of an elastomer and a second one of the composite structures is comprised of a second column formed of ePTFE and a second column filler formed of an elastomer.

22. The artificial intervertebral disc of claim 21, wherein the first composite structure and the second composite structure are configured such that the first composite structure and the second composite structure have associated in combination therewith, in at least one axis, a load versus deflection behavior substantially similar to that of a substantially healthy human intervertebral disc.

23. The artificial intervertebral disc of claim 22, wherein the load versus deflection behavior is selected from the group of: (a) dynamic behavior, which dynamic behavior is a function of a time rate application of load; (b) kinematic behavior; and (c) static behavior.

24. The artificial intervertebral disc of claim 22, wherein the load versus deflection behavior includes a non-linear relationship between an amount of force

required to compress the first composite structure and the second composite structure and a deflection of the first composite structure and the second composite structure.

25. The artificial intervertebral disc of claim 24, wherein a stiffness of each of the first composite structure and the second composite structure increases as each of the first composite structure and the second composite structure is compressed.

26. The artificial intervertebral disc of claim 21, wherein the artificial intervertebral disc is configured to be implanted by at least one method selected from the group of: (a) posterior implantation; and (b) anterior implantation.

27. An artificial intervertebral disc, comprising:
a first anchor member;
a second anchor member; and
a substantially solid chord of ePTFE disposed between the first anchor member and the second anchor member.

28. An artificial intervertebral disc, comprising:
a first assembly including:
(a) a first anchor member;
(b) a second anchor member; and
(c) a composite structure disposed between the first anchor member of the first assembly and the second anchor member of the first assembly, which composite structure of the first assembly is comprised of a column formed of ePTFE and a column filler formed of an elastomer; and
a second assembly including:
(a) a first anchor member;
(b) a second anchor member; and
(c) a composite structure disposed between the first anchor member of the second assembly and the second anchor member of the second assembly, which composite

structure of the second assembly is comprised of a column formed of ePTFE and a column filler formed of an elastomer.

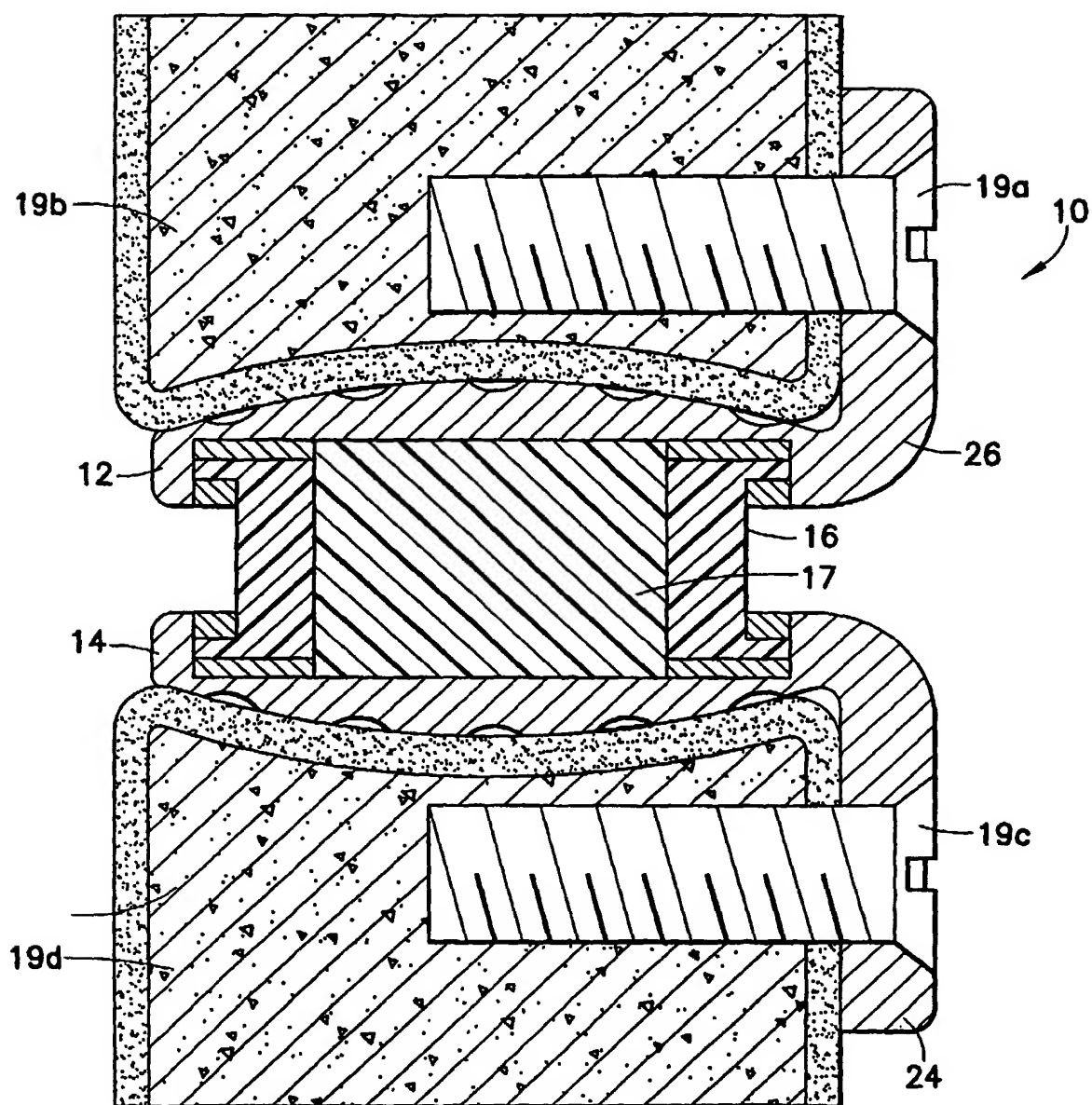


FIG. 1

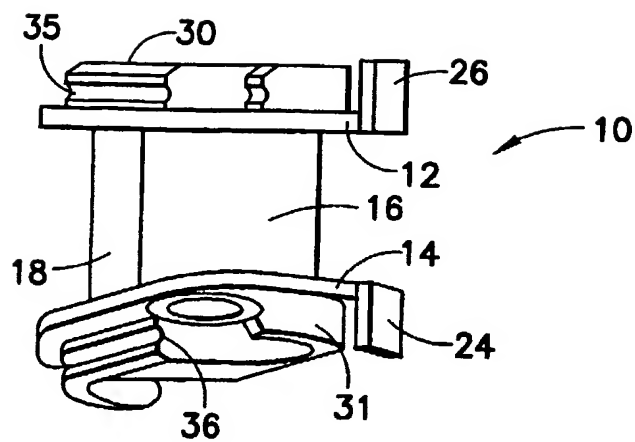


FIG. 2A

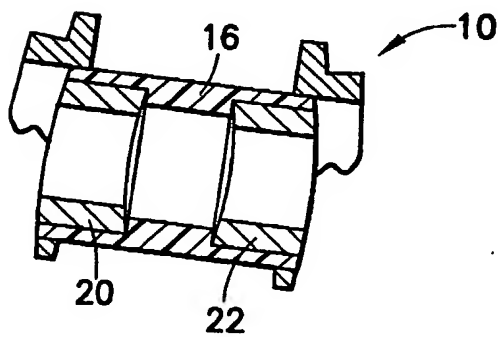


FIG. 2B

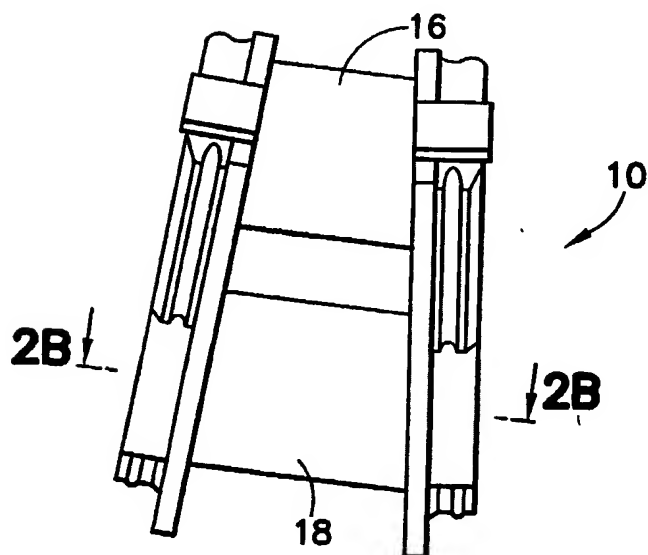


FIG. 2C

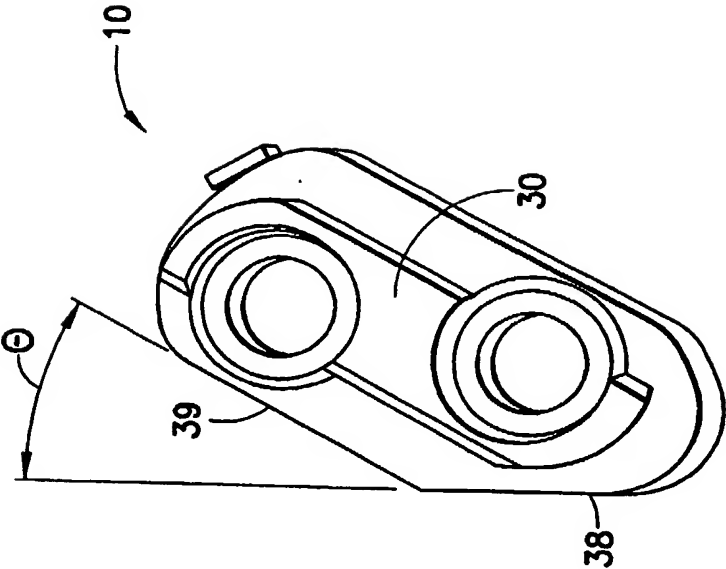


FIG. 2E

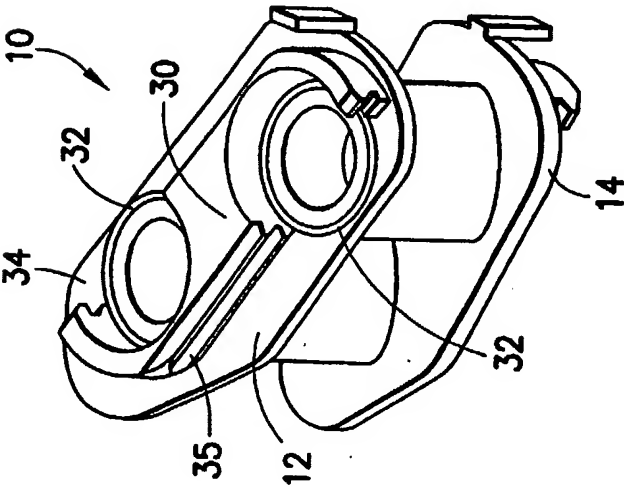


FIG. 2D

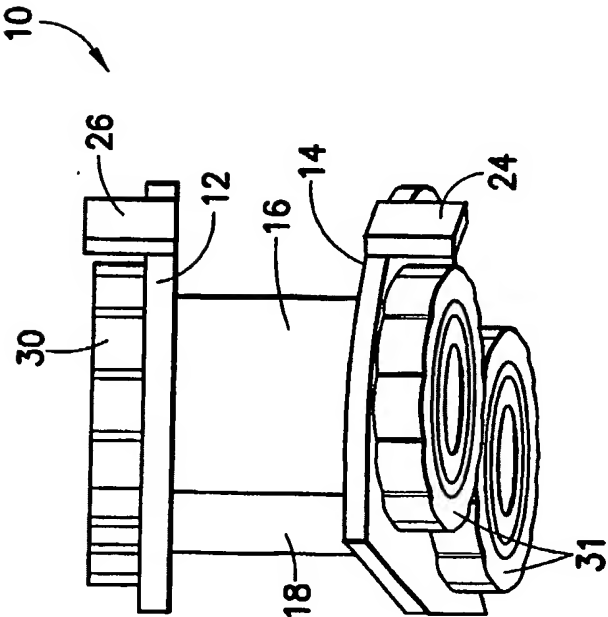


FIG. 3A

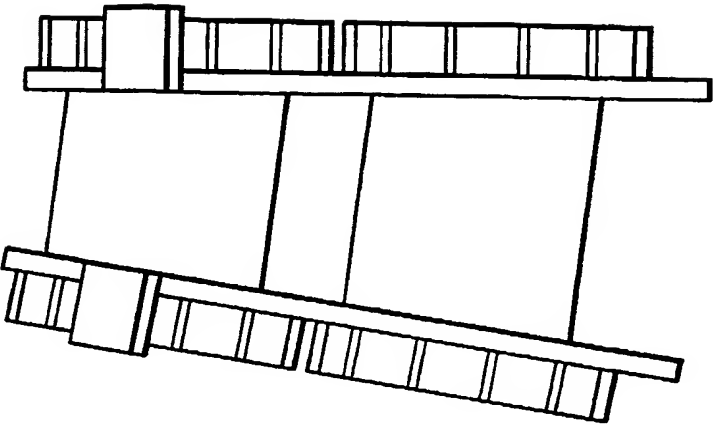


FIG. 3B

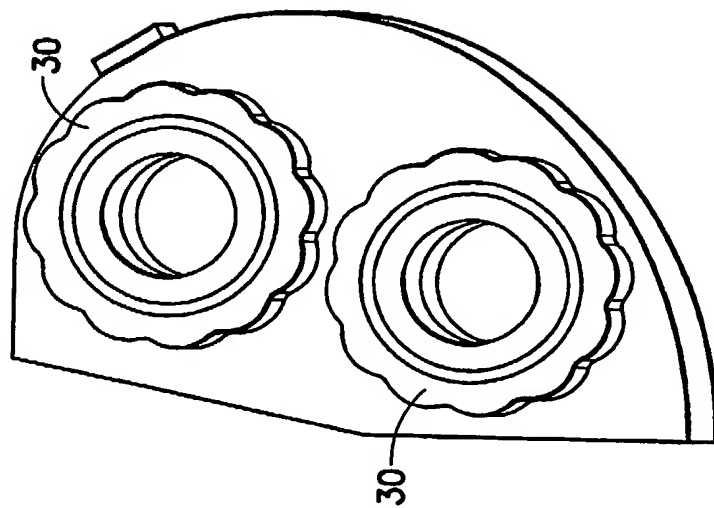


FIG. 3D

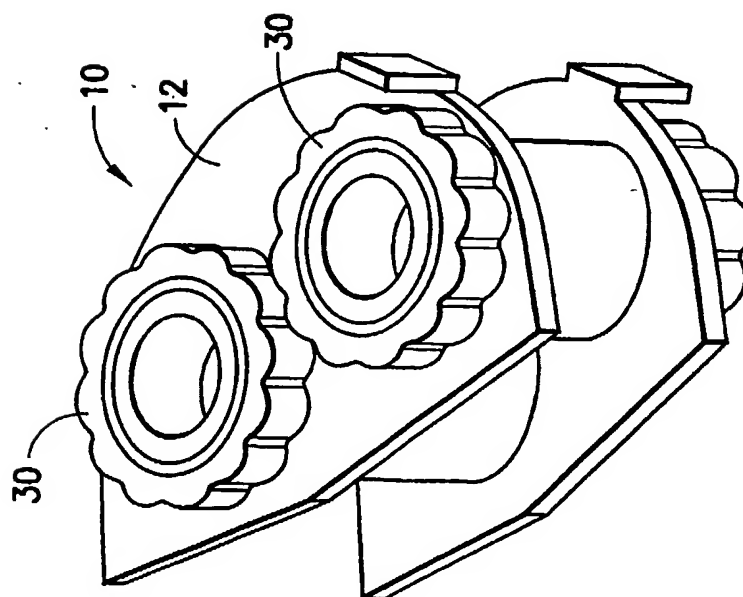


FIG. 3C

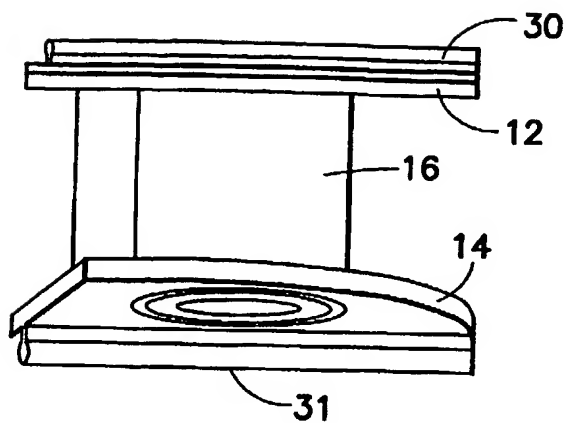


FIG. 4A

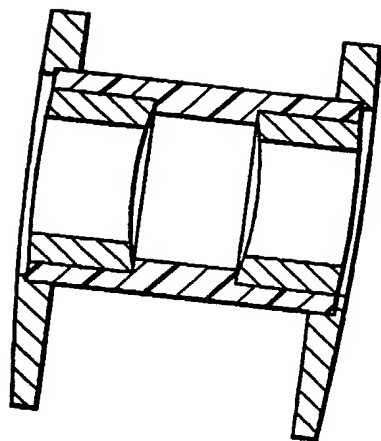


FIG. 4B

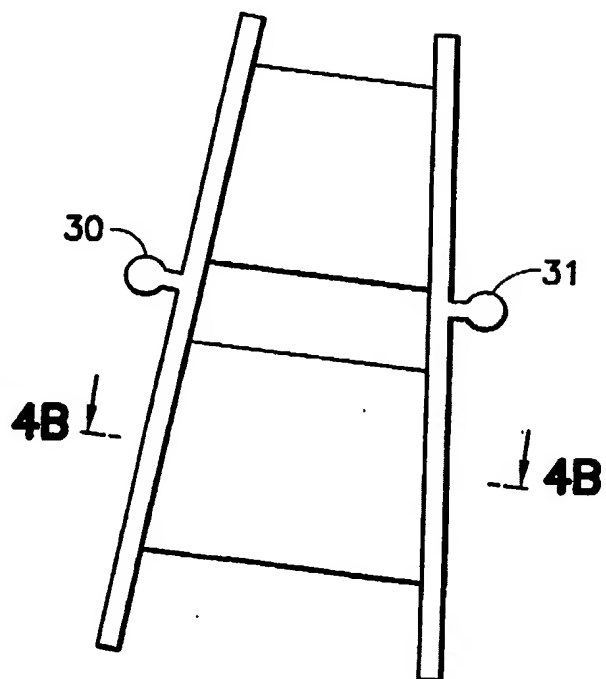


FIG. 4C

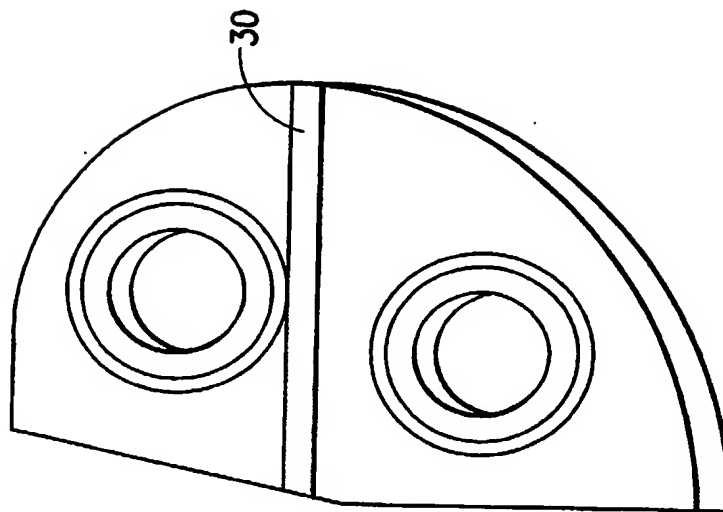


FIG. 4E

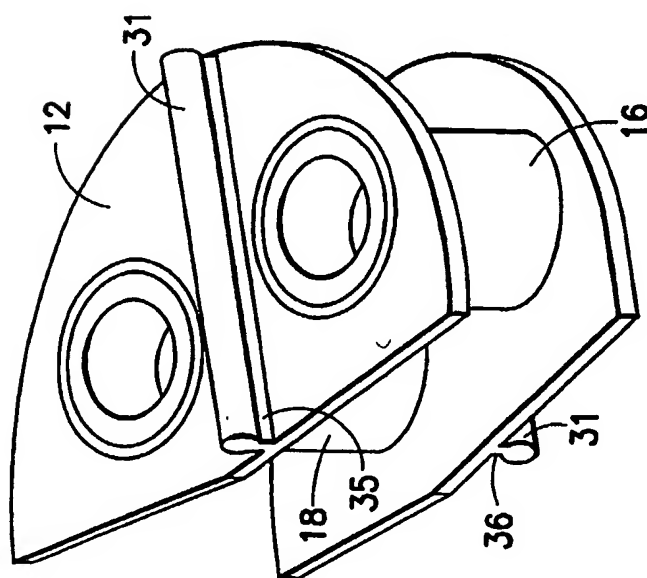


FIG. 4D

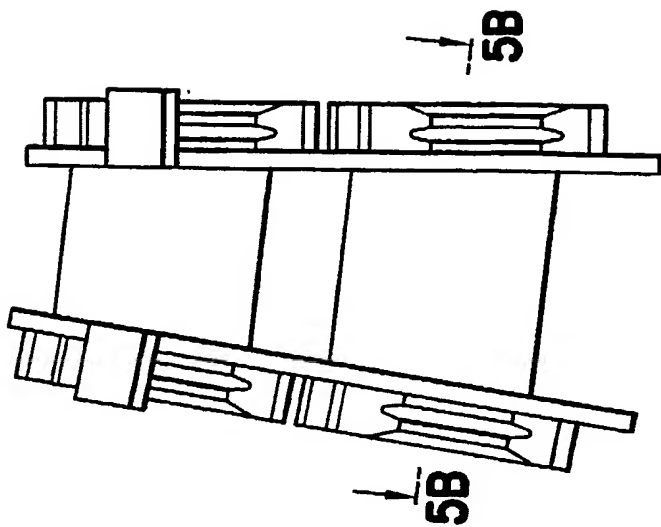


FIG. 5C

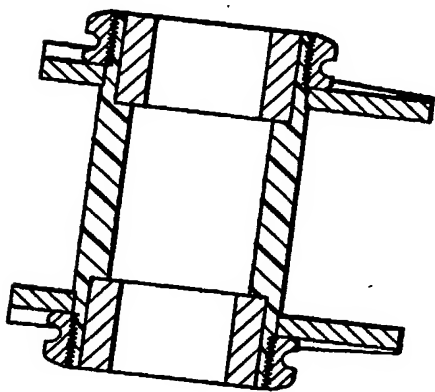


FIG. 5B

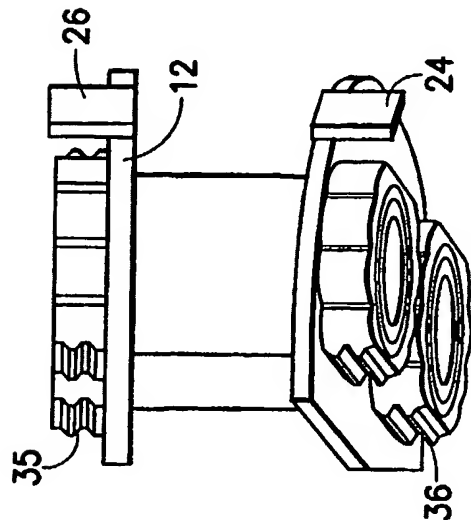


FIG. 5A

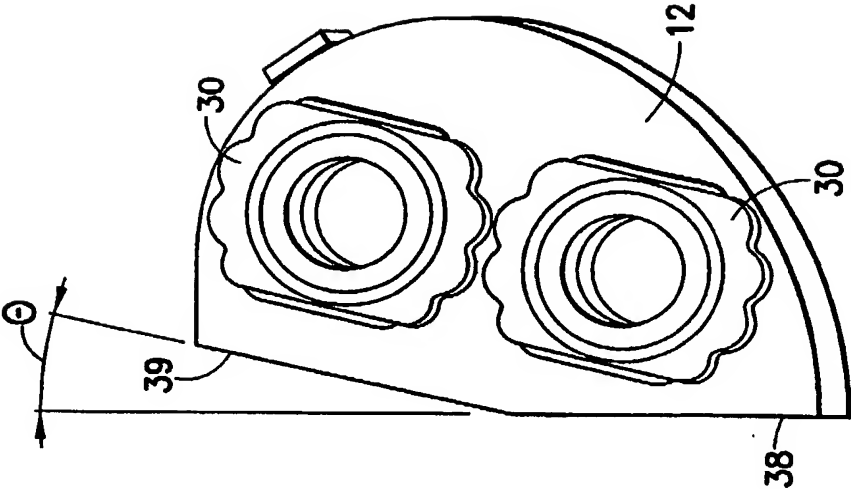


FIG. 5E

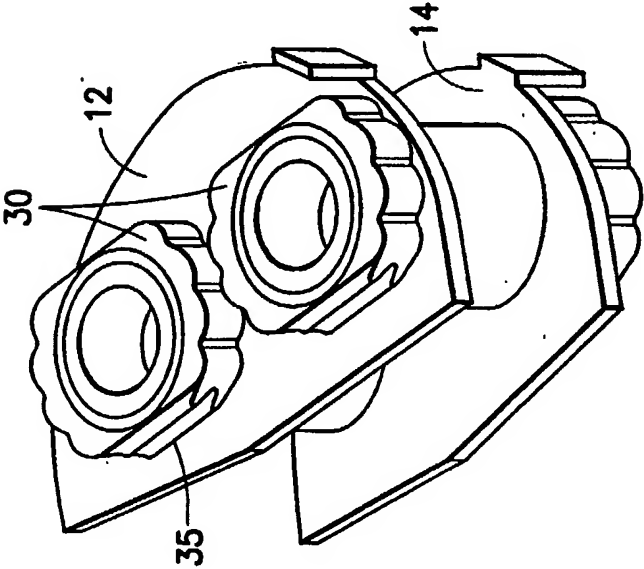


FIG. 5D

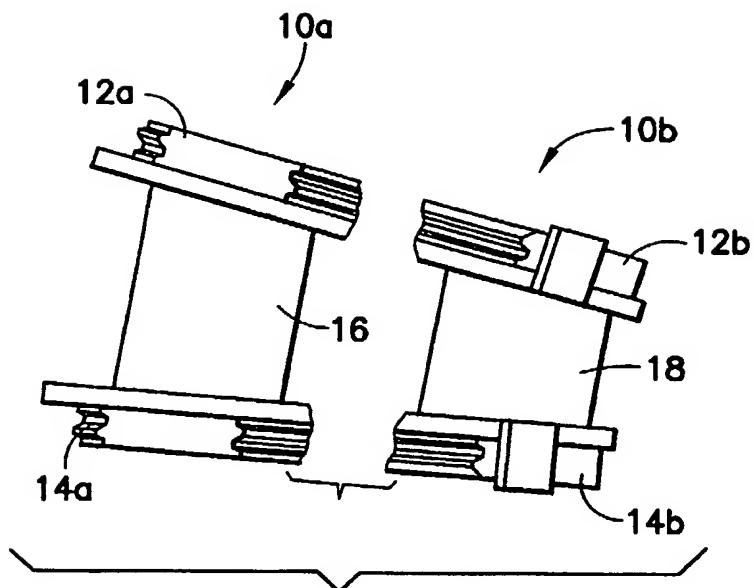


FIG. 6

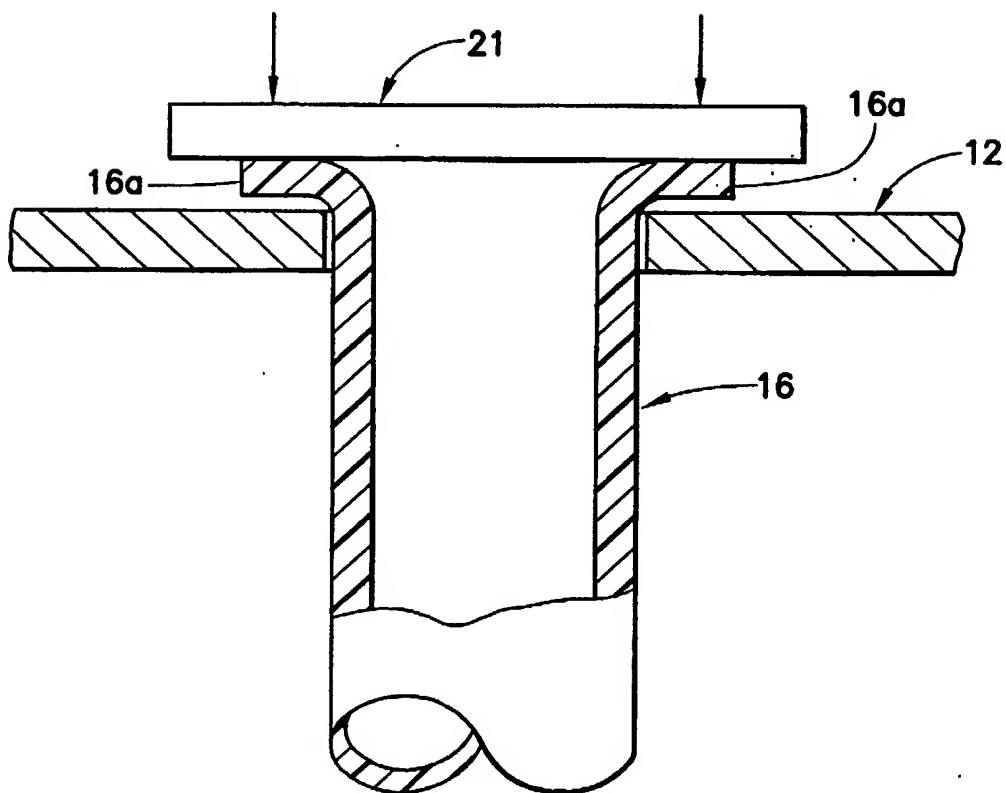


FIG. 7

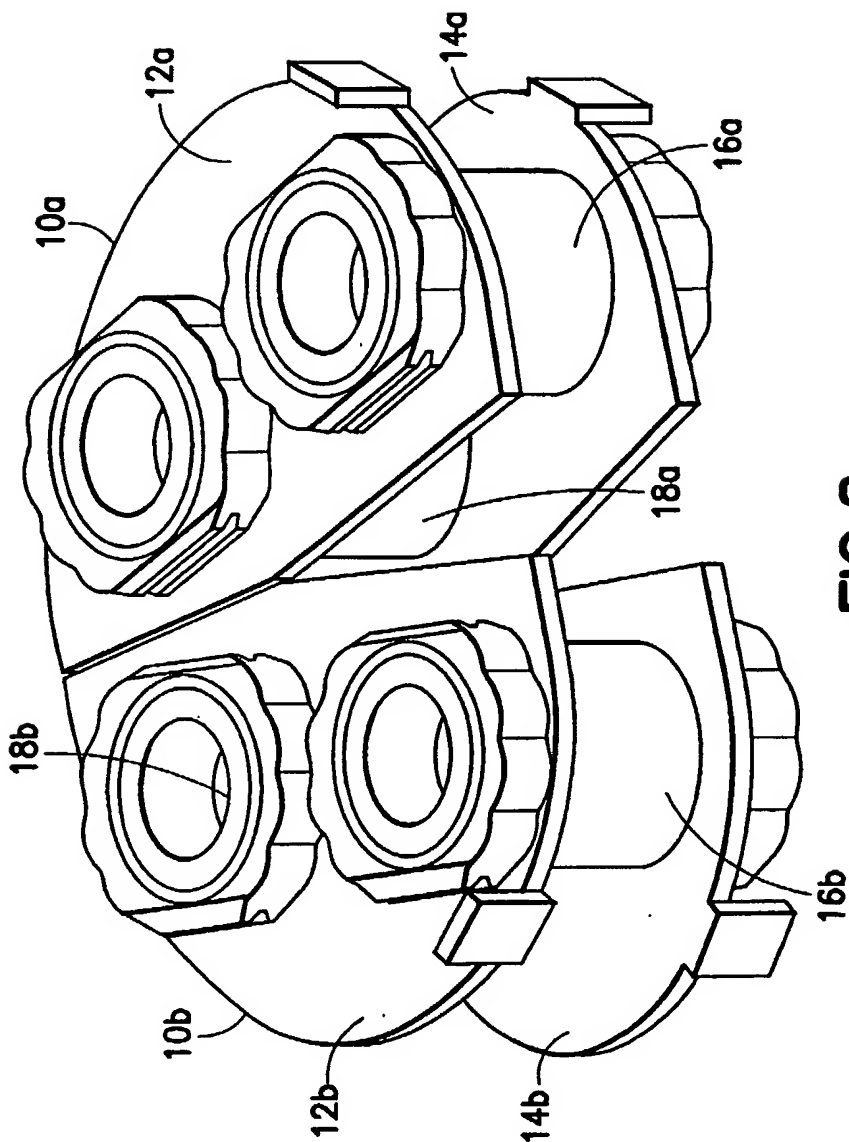


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/12872

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/44

US CL : 623/17.11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.11, 17.16, 17.15

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST BRS search terms: eptfe and (623/17.11 or 17.15 or 17.16)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,865,846 A (BRYAN et al) 02 February 1999 (02.02.1999), see Figures 3 and 4 as well as column 3, line 52 to column 4, line 55.	1-3, 6-11, 20, 27, and 28
A	US 5,674,294 A (BAINVILLE et al) 07 October 1997 (07.10.1997), see Figures 2 and 3 as well as column 3, line 12 to column 4, line 32.	1-28
A	US 4,911,718 A (LEE et al) 27 March 1990 (27.03.1990), see Figures 1 to 3 and 6 to 11 as well as column 3, line 51 to column 4, line 49.	1-28

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

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document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

07 August 2003 (07.08.2003)

Date of mailing of the international search report

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Commissioner for Patents
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Alexandria, Virginia 22313-1450

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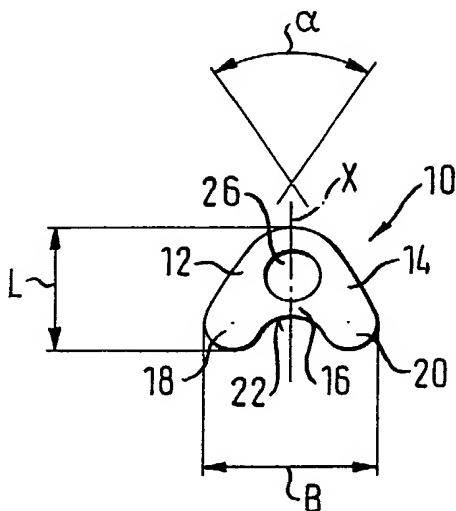
Veröffentlicht:

- mit internationalem Recherchenbericht
- vor Ablauf der für Änderungen der Ansprüche geltenden Frist; Veröffentlichung wird wiederholt, falls Änderungen eintreffen

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(54) Title: VERTEBRAL COLUMN IMPLANT CONSISTING OF BONE MATERIAL

(54) Bezeichnung: WIRBELSÄULENIMPLANTAT AUS KNOCHENMATERIAL



(57) Abstract: The invention relates to a vertebral column implant for intercorporeal fusion to the vertebral column. Said implant consists of a body produced from preserved bone material, whose size is adapted to the vertebral interstice between adjacent vertebrae that is formed once the vertebral interbody has been removed. The vertebral column implant exhibits an improved distribution of forces.

(57) Zusammenfassung: Ein Wirbelsäulenimplantat zur interkorporellen Fusion an der Wirbelsäule besteht aus einem Körper aus konserviertem Knochenmaterial, der in seiner Grösse an den nach Ausräumung des Wirbelzwischenkörpers vorhandenen Wirbelzwischenraum zwischen benachbarten Wirbeln angepasst ist. Das Wirbelsäulenimplantat weist eine verbesserte Kraftverteilung auf.



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Tutogen Medical GmbH

T 3313PWO – Cs/Fa

5

WIRBELSÄULENIMPLANTAT AUS KNOCHENMATERIAL

10 Die vorliegende Erfindung betrifft ein Implantat zur Verbindung von Knochen und insbesondere ein Wirbelsäulenimplantat zur interkorporellen Fusion von Wirbelknochen, das zwischen zwei zu fusionierende Wirbelknochen eingesetzt wird (vgl. DE-A-199 52 939).

15 Die Aufgabe der vorliegenden Erfindung besteht darin, ein Implantat zur Fusion von Knochen zu schaffen, das eine verbesserte Kraftverteilung zwischen zwei zu fusionierenden Wirbelknochen gewährleistet.

Die Lösung dieser Aufgabe erfolgt durch die Merkmale des Anspruchs 1.

20

Ein besonderer Vorteil des Wirbelsäulenimplantats gemäß der Erfindung ist durch das verwendete Material gegeben, das aufgrund seines biologischen Ursprungs und seiner Konservierung keinen Fremdkörper darstellt.

Darüber hinaus ergibt sich durch A-förmige Gestaltung mit zwei Schenkeln der Vorteil, dass das Implantat der Form der Kanten von Wirbelkörpern, insbesondere von Halswirbelkörpern, angepasst ist und somit beim
25 Einschieben in den Zwischenwirbelraum automatisch in die richtige Position kommt. Durch die spezielle erfindungsgemäße Form ist das Implantat

besonders gut an die natürliche Form der Wirbelkörperendplatten angepasst und bietet so aufgrund der A-Form die größtmögliche Kontaktfläche zu den Endplatten. Dadurch erfolgt eine mehr physiologische Verteilung der Kräfte wodurch Druckspitzen und ein durch diese bedingtes Einsinken des Implantates in die Wirbelkörper vermieden werden.

Besonders vorteilhaft ist die A-Form zudem, da hierdurch sowohl zwischen den Enden der Schenkel wie auch in der zentralen Öffnung lose eingebrachtes Knochenpulver in den Zwischenwirbelraum mitgenommen werden kann. Auf diese Weise kann beim Einschieben des Implantats in den Zwischenwirbelraum automatisch Knochenpulver oder spongiöser Knochen oder dergleichen in den Bereich des Implantats eingebracht werden.

In der Beschreibung, der Zeichnung und den Unteransprüchen sind weitere vorteilhafte Ausgestaltungen des Wirbelsäulenimplantats gemäß der vorliegenden Erfindung angegeben.

Bei einer ersten vorteilhaften Ausgestaltung des erfindungsgemäßen Wirbelsäulenimplantats weist der Körper ausschließlich abgerundete Außenkanten auf. Eine solche Gestaltung des Körpers erleichtert die Applikation des Wirbelsäulenimplantats zwischen den zu fusionierenden Wirbelkörpern, indem die Abrundungen ein Verkanten des Implantats während der Applikation verhindern.

25

Nach einer weiteren vorteilhaften Ausführungsform der Erfindung weisen die Schenkel des Körpers eine konvex gekrümmte Außenkontur auf. Durch eine solche Gestaltung der äußeren Flächen erfolgt eine besonders

gute Anpassung an Wirbelkörperendplatten. Auch können die Enden der Schenkel abgerundet, insbesondere etwa halbkreisförmig abgerundet sein, was das Einsetzen des Implantats sowie dessen leichte und korrekte Positionierung begünstigt.

5

Nach einer weiteren Ausbildung der Erfindung weist die durch die Schenkel und den Quersteg gebildete Öffnung eine abgerundete, insbesondere eine etwa kreisförmige Umfangskontur auf. Eine derart geformte Mittelöffnung lässt sich einerseits besonders einfach herstellen, andererseits ist
10 hierdurch das Implantat mit einer besonders hohen Stabilität versehen.

Nach einer weiteren Ausbildung der Erfindung kann sich die durch die Schenkel und den Quersteg gebildete Mittelöffnung nicht durchgehend von der Vorderseite zur Rückseite des Körpers erstrecken. Beispielsweise
15 kann diese Öffnung mit einem Boden oder mit einem Zwischenboden versehen sein, wodurch einerseits die Stabilität des Körpers erhöht und andererseits ein Aufnahmeraum für Knochenpulver gebildet werden kann.

Nach einer weiteren Ausbildung der Erfindung kann die Außenkontur des Körpers im Bereich des Querstegs und der sich daran anschließenden
20 freien Enden der Schenkel einen zentralen konkaven Abschnitt aufweisen. Dieser Abschnitt kann dazu dienen, ebenfalls beim Einbringen des Implantats in den Zwischenwirbelraum Knochenpulver oder Knochenspäne einzubringen.

25

Nach einer weiteren Ausbildung der Erfindung schließen die Außenflächen der beiden Schenkel miteinander einen Winkel von etwa 40 bis 70° ein. Hierdurch erfolgt eine besonders gute Anpassung an den Zwischenwirbel-

raum zwischen benachbarten Halswirbeln. Durch eine derartige Krümmung des Implantats ist somit automatisch eine korrekte Positionierung gegeben. Sofern das Wirbelsäulenimplantat, wie nach einer weiteren vorteilhaften Ausführungsform, einen trapezförmigen Querschnitt aufweist, ist hierdurch auch die Wiederherstellung der physiologischen Krümmung der Wirbelsäule möglich.

Bevorzugt ist das erfindungsgemäße Wirbelsäulenimplantat im Wesentlichen symmetrisch ausgebildet. Es ist jedoch auch eine asymmetrische Formgebung möglich, bei der sich die Gestaltung der beiden Schenkel voneinander unterscheidet.

Nach einer weiteren vorteilhaften Ausführungsform kann der Körper aus kompaktem Knochenmaterial bestehen, wobei sich in der durch die Schenkel und den Quersteg gebildeten Öffnung spongiöses Knochenmaterial befindet. Durch einen derartigen "Innenkern" aus Spongiosa kann die Fusion der benachbarten Wirbelknochen erleichtert werden.

Nach einer weiteren Ausbildung der vorliegenden Erfindung können an dem Körper Aufnahmeöffnungen auf einer oder mehreren Seiten des Körpers vorgesehen sein. In diese Bohrungen können dann Applikationswerkzeuge eingeführt werden, um das Implantat positionsgenau zwischen die zu fusionierenden Wirbel einzubringen.

Der Körper kann erfindungsgemäß aus prozessiertem, konserviertem und sterilem Knochenmaterial humanen Ursprungs, so genanntem Allograft, oder aus prozessiertem, konserviertem und sterilem Knochenmaterial tierischen Ursprungs, so genanntem Xenograft bestehen. Der Körper kann

aus massivem kortikalem oder auch aus massivem spongiösem Knochenmaterial gefertigt werden, beispielsweise aus Humerus, Femur, Tibia, oder aus anderen Knochen sowohl von verstorbenen Menschen als auch von Tieren, insbesondere aus Knochenmaterial vom Rind, hergestellt werden.

5

Als Material wird für das Wirbelsäulenimplantat gemäß der vorliegenden Erfindung ein geeignetes allogenes oder xenogenes Knochenmaterial derart prozessiert, dass es konserviert, lagerfähig sowie steril ist und bestimmungsgemäß eingesetzt werden kann. Die Konservierung des Knochenmaterials kann beispielsweise mittels Gefriertrocknung erfolgen. Ein
10 anderes bevorzugtes Verfahren der Herstellung des Knochenmaterials ist die Prozessierung durch vorzugsweise Lösungsmitteldehydratisierung von nativem Knochenmaterial mittels eines organischen, mit Wasser mischbaren Lösungsmittels, z.B. Methanol, Ethanol, Propanol, Isopropanol, Aceton, Methyl-Ethylketon oder Gemischen dieser Lösungsmittel. Die Konser-
15 vierung und Sterilisation des Knochenmaterials nach diesem Verfahren ist auch Gegenstand des Patents DE 29 06 650, dessen Inhalt durch diese Bezugnahme in die Offenbarung der vorliegenden Anmeldung aufgenommen wird.

20

Dieses Verfahren dient der Herstellung von Transplantatkonserven und ermöglicht eine Dehydratisierung und Freilegung bis in den Feinbau der Fibrille des Knochenmaterials, so dass das prozessierte Knochenmaterial im histologischen Bild eine dem natürlichen Knochen sehr ähnliche mor-
25 phologische Struktur aufweist und somit die gewünschten Eigenschaften des Knochenmaterials erhalten bleiben. Dieses Verfahren der Lösungsmitteldehydratisierung hat außerdem den Vorteil, dass im Vergleich zur

Gefriertrocknung ein wesentlich geringerer apparativer Aufwand erforderlich ist.

5 Ferner kann das Knochenmaterial auch durch Lösungsmitteldehydratisierung von nativem Knochen mit anschließender terminaler Sterilisation, insbesondere durch Bestrahlung mit Gamma-Strahlen erzeugt werden. Alternativ kann das spongiöse Knochenmaterial durch aseptische Prozessierung von Knochenmaterial ohne terminale Sterilisation erzeugt werden. Das Ausgangsmaterial des erfindungsgemäßen Knochenimplantats ist
10 menschlicher oder tierischer Knochen von ausreichender Größe.

Zur Entfernung der Antigenität wird der Knochen einer osmotischen Behandlung unterzogen. Weiterhin wird zur Denaturierung löslicher Proteine eine oxidative Behandlung durchgeführt. Zur Optimierung der
15 Virusinaktivierung kann eine pH-Absenkung auf pH 3 erfolgen oder eine Behandlung mit Natronlauge oder einer anderen DNA/RNA zerstörenden Substanz. Der Wasserentzug erfolgt durch organische Lösungsmittel, vorzugsweise Aceton. Die abschließende Sterilisation erfolgt durch energiereiche Strahlung, vorzugsweise γ -Strahlen mit einem Dosismaximum
20 von 25 kGy.

Ein so behandelter Knochen behält seinen natürlichen Mineral-Kollagen-Verbund und dessen Eigenschaften. Darüber hinaus ist ein so behandelter Knochen umbaufähig.

25

Das erfindungsgemäße Wirbelsäulenimplantat kann insbesondere durch ein Verfahren vorteilhaft hergestellt werden, bei dem menschlicher oder tierischer Tibiaknochen quer zur Knochenlängsachse in zumindest eine

Scheibe gesägt wird, wobei aus dieser Scheibe anschließend zwei Wirbelsäulenimplantatkörper gearbeitet werden. Dieses Verfahren beruht auf der Erkenntnis, dass die Außenkontur des Tibiaknochens derjenigen der erfindungsgemäßen Wirbelsäulenimplantatkörper sehr ähnlich ist, so dass
5 sich die Form des erfindungsgemäßen Implantatkörpers vorteilhaft in den Tibiaknochen einbeschreiben lässt.

Nachfolgend wird die vorliegende Erfindung rein exemplarisch anhand von Ausführungsbeispielen eines erfindungsgemäßen Wirbelsäulenimplantats
10 unter Bezugnahme auf die beigefügten Zeichnungen beschrieben. Es zeigen:

- Fig. 1 eine perspektivische Ansicht einer Ausführungsform eines Wirbelsäulenimplantats gemäß der Erfindung;
15
- Fig. 2 eine vergrößerte Darstellung der Oberflächentextur des Implantats von Fig. 1;
- Fig. 3 eine Draufsicht auf eine weitere Ausführungsform eines Wirbelsäulenimplantats gemäß der Erfindung;
20
- Fig. 4 mögliche Querschnittsformen des erfindungsgemäßen Wirbelsäulenimplantats;
- 25 Fig. 5 einen Querschnitt durch einen Tibiaknochen mit einbeschriebenen Konturen des erfindungsgemäßen Wirbelsäulenimplantats; und

Fig. 6 eine Draufsicht auf Ausführungsformen eines Wirbelsäulen-
implantats gemäß der vorliegenden Erfindung mit möglichen
Bohrungen für die Aufnahme eines Applikationswerkzeugs.

- 5 In den Figuren bezeichnen die gleichen Bezugszeichen jeweils die gleichen
Komponenten der dargestellten Ausführungsformen.

Das in Fig. 1 dargestellte Ausführungsbeispiel eines erfindungsgemäßen
Wirbelsäulenimplantats umfasst einen Körper 10, der beispielsweise aus
10 kortikalem, diaphysärem Knochenmaterial z.B. humanen Ursprungs
besteht.

Der in Fig. 1 dargestellte Körper 10 weist zwei unter einem spitzen Winkel
 α (Fig. 3) verlaufende Schenkel 12 und 14 auf, wobei zwischen den Schen-
15 keln 12 und 14 ein die Schenkel verbindender Quersteg 16 vorgesehen ist,
so dass der Körper 10 in Draufsicht im Wesentlichen die Form eines A
aufweist.

Wie Fig. 1 und insbesondere Fig. 3 zeigt, weist die Außenkontur des "A"
20 ausschließlich abgerundete Kanten auf. Außerdem weisen die Schenkel 12
und 14 eine leicht konvex gekrümmte Außenkontur auf. Wie ferner zu
erkennen ist, ist die Breite der Schenkel 12 und 14 über der Längserstre-
ckung nicht einheitlich. Vielmehr sind die beiden Schenkel 12 und 14 an
ihren äußeren freien Enden relativ breit. Im Bereich des Scheitels des A
25 liegt demgegenüber eine geringere Breite der Schenkel vor.

Die freien Enden 18, 20 der Schenkel 12 und 14 (Fig. 3) sind etwa halb-
kreisförmig abgerundet. Die Außenkontur des Körpers 10 im Bereich des

Querstegs 16 und der sich daran anschließenden freien Enden 18, 20 der Schenkel 12, 14 weist einen konkaven Abschnitt 22 auf, der stetig in die ansonsten vollständig konvex gekrümmte Umfangskontur des Körpers 10 übergeht.

5

Wie die Fig. 1 und 2 zeigen, kann die dargestellte Oberseite oder auch die Unterseite des Körpers 10 eine Riffelung 14 aufweisen, die eine Dislokation des Implantats im Wirbelzwischenraum verhindert.

- 10 Die in den Figuren dargestellten Ausführungsformen des erfindungsgemäßen Wirbelsäulenimplantats sind zu dessen Mittelachse X symmetrisch ausgebildet. Es sei jedoch auch darauf hingewiesen, dass auch unsymmetrische Ausführungsformen denkbar sind, bei denen beispielsweise die Länge oder die Gestaltung der beiden Schenkel 18 und 20 unterschiedlich
15 ist.

- Wie die Figuren ferner zeigen, ist durch die beiden Schenkel 12 und 14 sowie den Quersteg 16 eine Öffnung 26 gebildet, die beim dargestellten Ausführungsbeispiel von der Vorderseite zur Rückseite des Körpers 10
20 durchgehend und mit kreisförmigem Querschnitt ausgebildet ist.

- Fig. 3 zeigt eine Draufsicht auf eine Ausführungsform eines Körpers 10 eines Wirbelsäulenimplantats, wobei die Breite B, die Länge L und die Höhe H (vgl. Fig. 4b)) wie folgt gewählt werden können: Bei lumbalen
25 Anwendungen kann die Länge L etwa 30 bis 60 mm, die Breite B etwa 8 bis 20 mm und die Höhe H etwa 6 bis 18 mm betragen. Bei cervikalen Anwendungen kann die Länge L etwa 8 bis 18 mm, die Breite B etwa 8 bis 18 mm und die Höhe H etwa 4 bis 15 mm betragen. Bei dem in Fig. 3

dargestellten Ausführungsbeispiel beträgt die Länge L etwa 11 mm, die Breite B etwa 14 mm und die Höhe H etwa 8 mm.

Der Winkel α , den die Außenflächen der beiden Schenkel 12 und 14 miteinander einschließen, liegt bevorzugt in einem Bereich von etwa 40 bis 70°. Bei dem in Fig. 3 dargestellten Ausführungsbeispiel beträgt der Winkel α etwa 55°.

Fig. 4a) und 4b) zeigen mögliche Querschnittsformen des Körpers 10 entlang der Mittelachse X von Fig. 3. Wie aus Fig. 4a) erkennbar ist, kann der Querschnitt des Körpers 10 trapezförmig oder aber, wie in Fig. 4b) gezeigt ist, im Wesentlichen rechteckig sein. Die in Fig. 4a) dargestellten schräg verlaufenden Seiten können unter einem Winkel von etwa 3 bis 6 ° von der Rechteckform abweichen. An dieser Stelle sei nochmals darauf hingewiesen, dass die Darstellung der Fig. 4 nicht maßstäblich zu denjenigen von Fig. 3 ist.

Grundsätzlich besteht die Möglichkeit, dass das erfindungsgemäße Wirbelsäulenimplantat massiv ausgebildet wird, beispielsweise aus kortikalem oder aus spongiösem Knochen. Eine alternative Ausführungsform der Erfindung sieht vor, dass das Wirbelsäulenimplantat - ebenfalls aus kortikalem oder spongiösem Knochen - als Hohlkörper ausgebildet wird.

Fig. 5 zeigt im Querschnitt einen Tibiaknochen T, wobei die Außenkonturen zweier Wirbelsäulenimplantate 10 gemäß der Erfindung in den Tibiaquerschnitt einbeschrieben sind. Wie gut zu erkennen ist, eignet sich der Tibiaknochen in besonders guter Weise zur Herstellung des erfindungsgemäßen Wirbelsäulenimplantatkörpers, da die Außenkontur und die

Innenkontur des Tibiaknochens T der Außenkontur des Körpers 10 nahezu entspricht. Bei einem besonders vorteilhaften Verfahren zur Herstellung des Körpers 10 wird deshalb menschlicher oder tierischer Tibiaknochen quer zu dessen Längsachse in Scheiben gesägt, wobei anschließend
5 zwei der in den Figuren dargestellten Körper 10 aus der so gewonnenen Knochenscheibe herausgearbeitet werden, beispielsweise durch Fräsen.

Die Fig. 6a) bis c) zeigen verschiedene Ausführungsformen eines Wirbelsäulenimplantats 10 mit Lochbohrungen 28, 30 für die Aufnahme in ein
10 Applikationswerkzeug. Die Lochbohrungen können unterschiedliche Tiefe aufweisen und in verschiedenen Winkeln zueinander stehen. Auch ist es möglich, lediglich eine Lochbohrung vorzusehen. Grundsätzlich sind die Lochbohrungen in derjenigen Ebene vorgesehen, in der das Wirbelsäulenimplantat in den Wirbelzwischenraum eingeführt werden kann. Je nach
15 Applikationsart werden die Lochbohrungen 28, 30 an den freien Enden der Schenkel 12, 14 (Fig. 6a)), im Bereich des spitzen Endes des "A" (Fig. 6b)) oder an einer Seite der Schenkel 12, 14 (Fig. 6c)) positioniert.

Bezugszeichenliste

5	10	Körper
	12, 14	Schenkel
	16	Quersteg
	18, 20	freie Enden der Schenkel
	22	zentraler konkaver Abschnitt
10	24	Riffelung
	26	Öffnung
	28, 30	Lochbohrung
15	B	Breite
	H	Höhe
	L	Länge
	T	Tibiaknochen
	X	Mittelachse
	α	Winkel zwischen den Schenkeln
20		

Ansprüche

1. Wirbelsäulenimplantat zur interkorporellen Fusion an der Wirbelsäule, bestehend aus einem Körper (10) aus konserviertem Knochenmaterial, der einen im wesentlichen rechteckigen oder trapezförmigen Querschnitt besitzt, und der in seiner Größe an den nach Ausräumung des Wirbelzwischenkörpers vorhandenen Wirbelzwischenraum zwischen benachbarten Wirbeln angepasst ist, wobei der Körper (10) zwei unter einem spitzen Winkel (α) verlaufende Schenkel (12, 14) und einen die Schenkel (12, 14) verbindenden Quersteg (16) aufweist, so dass der Körper (10) in Draufsicht im Wesentlichen die Form eines A aufweist.
2. Wirbelsäulenimplantat nach Anspruch 1, dadurch gekennzeichnet, dass die Außenkontur des "A" ausschließlich abgerundete Kanten aufweist.
3. Wirbelsäulenimplantat nach Anspruch 1, dadurch gekennzeichnet, dass die Schenkel (12, 14) eine konvex gekrümmte Außenkontur aufweisen.

4. Wirbelsäulenimplantat nach Anspruch 1,
dadurch gekennzeichnet, dass
die Enden (18, 20) der Schenkel (12, 14) insbesondere etwa halb-
kreisförmig abgerundet sind.

5

5. Wirbelsäulenimplantat nach Anspruch 1,
dadurch gekennzeichnet, dass
die durch die Schenkel (12, 14) und den Quersteg (16) gebildete
Öffnung (26) eine abgerundete, insbesondere eine etwa kreisförmige
Umfangskontur aufweist.

10

6. Wirbelsäulenimplantat nach Anspruch 1,
dadurch gekennzeichnet, dass
die durch die Schenkel (12, 14) und den Quersteg (16) gebildete Öff-
nung (26) sich nicht durchgehend von der Vorderseite zu der Rück-
seite des Körpers (10) erstreckt.

15

7. Wirbelsäulenimplantat nach Anspruch 1,
dadurch gekennzeichnet, dass
die Außenkontur des Körpers (10) im Bereich des Querstegs (16)
und der sich daran anschließenden freien Enden (18, 20) der
Schenkel (12, 14) einen zentralen konkaven Abschnitt (22) aufweist.

20

8. Wirbelsäulenimplantat nach Anspruch 1,
dadurch gekennzeichnet, dass
zumindest eine Außenfläche des Körpers (10) eine Riffelung (24)
aufweist, die eine Dislokation des Implantats im Wirbelzwischen-
raum verhindert.
- 5
9. Wirbelsäulenimplantat nach Anspruch 1,
dadurch gekennzeichnet, dass
die seitlichen Außenflächen der beiden Schenkel (12, 14) einen Win-
kel von etwa 40 -70° einschließen.
- 10
10. Wirbelsäulenimplantat nach Anspruch 1,
dadurch gekennzeichnet, dass
der Körper (10) symmetrisch ausgebildet ist.
- 15
11. Wirbelsäulenimplantat nach Anspruch 1,
dadurch gekennzeichnet, dass
der Körper (10) aus Kompakta besteht und dass sich in der durch
die Schenkel (12, 14) und den Quersteg (16) gebildeten Öffnung (26)
spongiöses Knochenmaterial befindet.
- 20
12. Wirbelsäulenimplantat nach Anspruch 1,
dadurch gekennzeichnet, dass
der Körper (10) aus konserviertem und sterilem Knochenmaterial
humanen oder tierischen Ursprungs, insbesondere aus konservier-
tem und sterilem bovinem Knochenmaterial besteht.
- 25

13. Verfahren zur Herstellung eines Wirbelsäulenimplantats nach zumindest einem der vorstehenden Ansprüche,
dadurch gekennzeichnet, dass
5 menschlicher oder tierischer Tibiaknochen quer zu dessen Längsachse in zumindest eine Scheibe gesägt wird, und dass anschließend aus dieser Scheibe zwei Körper (10) gearbeitet werden.

2 / 2

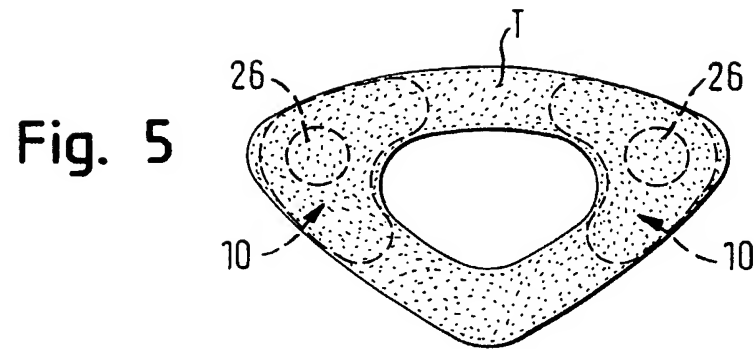
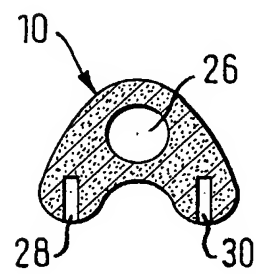
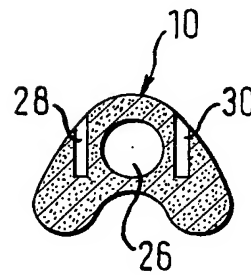


Fig. 6

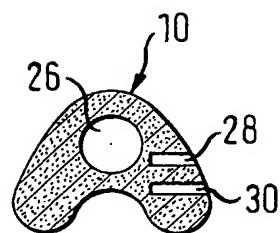
a)



b)



c)



INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 03/03452

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	page 2, paragraph 39 -page 3, paragraph 43; figures 1-9	13
Y	WO 00 19941 A (CAMBRIDGE SCIENT INC) 13 April 2000 (2000-04-13)	1-5,7-12
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A	US 5 989 289 A (HOECK JAMES VAN ET AL) 23 November 1999 (1999-11-23)	1-5,7-12
	column 5, line 7 -column 8, line 53	

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INTERNATIONAL SEARCH REPORT
Information on patent family members

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INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/EP 03/03452

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61F2/44

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

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Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)

IPK 7 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

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EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	US 2002/026242 A1 (MORRIS JOHN W ET AL) 28. Februar 2002 (2002-02-28)	1-5,7-12
A	Seite 2, Absatz 39 -Seite 3, Absatz 43; Abbildungen 1-9	13
Y	WO 00 19941 A (CAMBRIDGE SCIENT INC) 13. April 2000 (2000-04-13)	1-5,7-12
	Seite 7, Zeile 9 -Seite 8, Zeile 16; Abbildung 2	
A	US 5 989 289 A (HOECK JAMES VAN ET AL) 23. November 1999 (1999-11-23)	1-5,7-12
	Spalte 5, Zeile 7 -Spalte 8, Zeile 53	



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Bevollmächtigter Bediensteter

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Internationales Aktenzeichen
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SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ,
VC, VN, YU, ZA, ZM, ZW.

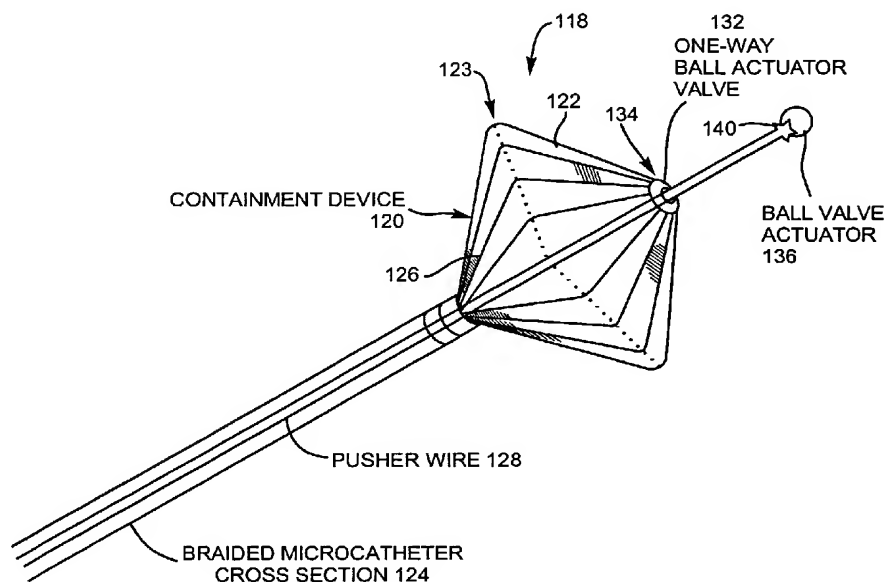
(84) Designated States (*regional*): ARIPO patent (GH, GM,
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European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,
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For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: TACTICAL DETACHABLE ANATOMIC CONTAINMENT DEVICE AND THERAPEUTIC TREATMENT SYSTEM



(57) Abstract: Devices and methods for the controlled delivery of therapeutic agents into bone and soft tissue to prevent the unin-
tentional migration of therapeutic agents from the treatment site. The containment device can be made of a fabric or membrane that
is porous, semi-porous, non-porous, bio-resorbable, or non-resorbable materials. A containment device is advanced to the interior
of the target structure and filled with a therapeutic agent. The containment device may be permanently or temporarily implanted.
Where permanent implantation is desired, the containment device may be detached via a severable junction.



WO 03/094805 A2

DESCRIPTIONTACTICAL DETACHABLE ANATOMIC CONTAINMENT DEVICE
AND THERAPEUTIC TREATMENT SYSTEMFIELD OF THE INVENTION

5 This invention relates to medical implants, and in particular, to detachable containment systems for implanting therapeutic materials in vivo.

BACKGROUND

10 Numerous bone conditions or spinal injury can cause painful collapse of vertebral bodies, including osteopenia (osteoporosis), vertebral hemangiomas, multiple myeloma, necrotic lesions (Kummel's Disease, Avascular Necrosis), metastatic disease and complications from steroid and non-steroidal anti-inflammatory drug (NSAID) use. Osteoporosis is a systemic, progressive and chronic disease that is usually characterized by low bone mineral density, deterioration of bony architecture, and reduced overall bone strength. Vertebral body compression fractures (VCF) are more common in people who
15 suffer from these medical indications, often resulting in pain, compromises to activities of daily living, and even prolonged disability. Likewise, degenerative and injured spinal disk rehabilitation (pharmacological or gene therapeutic) protocols to delay the progression of intradiscal diseases, or even to restore disk health and disk functions, are a part of contemporary research developments and emerging standards of care.

20 The science of spinal intervention has made great strides in recent years. On some occasions, spinal or poly-trauma patients experience VCFs that may be repaired by vertebroplasty and other spinal reconstructive means. Vertebroplasty, which literally means fixing the vertebral body, has been used in the United States since the mid-1990s to treat pain and progressive deterioration associated with VCF. Most often in this vertebroplasty
25 procedure, a bone cement, like opacified polymethylmethacrylate (PMMA), or other suitable biomaterial alternatives or combinations, is injected percutaneously into the bony architecture under radiographic guidance and controls. The hardening (polymerization) of the cement media or the mechanical interlocking of other biomaterials serve to buttress the bony vault of the vertebral body, providing both increased structural integrity and decreased potential for
30 painful micromotion and progressive collapse of the vertebrae and spinal column.

Bone tamps (bone balloons or Kyphoplasty™), a contemporary balloon-assisted vertebroplasty alternative for treatment of VCF, also involves injection of a bone cement into a mechanically created bone void within vertebral body. In this alternative vertebroplasty

procedure, a balloon tamp is first inserted into the structurally compromised vertebral body, often through a cannula. The bone balloon is then deployed under high pressure. The expanding balloon disrupts the cancellous bone architecture and physiological matrix circumferentially and directs the attendant bony debris and physiologic matrix toward the inner cortex of the vertebral body vault. The balloon tamp is then collapsed and removed, leaving a bony void or cavity. The remaining void or cavity is repaired by filling it with an appropriate biomaterial media, most often bone cement. In most cases, the treatment goals are to reduce or eliminate pain and the risk of progressive fracture of the vertebral body and its likely resulting morbidity, complications, and disability.

Although most of these interventional procedures are an improvement over previous conservative treatments that consisted of bed rest, pharmaceuticals, and/or cumbersome back braces, these methods still suffer from the complication of potential leakage of the therapeutic biomaterial repair media (bone cement, etc.) outside of the desired treatment zone.

Numerous risks are associated with these spinal interventional procedures. The risks and complications, which are related to the leakage of the biomaterial into structures that are intended to be preserved, may involve extravasation of the biomaterial into veins and/or lungs, infections, bleeding, rib or pedicle fracture, pneumothorax, increased pain, a range of soft and/or neural tissue impingement, paresis, and paralysis. Most clinicians prefer to focus or contain treatments to the injured or diseased tissues alone.

Disease and injury can also erode or violate the supporting and collateral soft tissues. In the case of an insult, disruption, disease, or injury to a joint construct (spinal column [e.g., spinal facet], hip, knee, elbow, fingers, ankle, shoulder, synovium, collateral ligaments, etc.), joint capsule, ligamentous structures, or cartilaginous (collagen based) tissues, it may be necessary to manage or contain physiological biomaterial, or other therapeutic media within the joint or anatomic structure. Likewise, primary and secondary spinal tumors may contribute to a loss of tissue (bony, etc.) integrity and strength. Therefore, these tumors may serve as indications for vertebroplasty and other interventional spinal augmentation. The treatment of many other diseases of the bone and other tissues can also be facilitated by treating the diseases from within and/or proximate to the target anatomy. For example, chemotherapeutic agents could be implanted in proximity to or within a tumor. Or in the case of a failed bony fusion (pseudoarthrosis), a reoperation and revision may be avoided through the introduction of biological agents into a containment device designed to promote bony healing. In particular, bone healing by interventional means may be facilitated by the implantation of osteophilic (osteoinductive or osteoconductive) materials, which are scaffolds

and/or materials used to stimulate or optimize bony healing. These materials include, but are not limited to, hydroxylapatite (HA), tri-calcium phosphate, biocoral, bioceramics, biomaterial granules, demineralized bone matrix (DBM), bone morphogenic proteins (BMPs), and collagen. Bone morphogenic proteins (BMPs), an active ingredient in DBM and a member of the TGF- β (transforming growth factor - β) super family, mediate developmental processes that include morphogenesis, differentiation, cell survival, and apoptosis. Although the role of TGF- β is not fully understood, its net effect is an increase in bone matrix. Other factors, such as insulin-like growth factors (IGF I and IGF II) and platelet derived growth factor are also important. Unfortunately, since these proteins have short biological half-lives, they must be maintained at the treatment zone in sufficient therapeutic concentrations in order to be effective. Therefore, dilution of the therapeutic agent due to the unintentional migration of the implanted material away from the therapeutic zone is also a major challenge to good patient outcomes.

Accordingly, it would be desirable to provide treatment systems and methods that contain and deliver implanted biomaterial or other pharmacological or treatment media at any time during the treatment cycle, while preventing the unintentional migration of the implanted materials and/or controlling the release of the implanted materials into the targeted tissue or cellular treatment zone.

SUMMARY OF THE INVENTION

This invention relates to medical implants, and in particular, containment systems for implanting therapeutic materials in vivo. The containment device of the present invention is especially appropriate, but not limited to VCF treatments. The containment device provides a barrier, preventing the unintentional migration of its augmentation, reconstructive, pharmacological, and therapeutic contents from the treatment site. In one embodiment, the containment device is an appropriately compliant, mechanically expandable, or self-expandable containment structure that can be filled with selected therapeutic materials. Alternatively, the containment device could be made of a semi-compliant or rigid material, as may be the case with many spinal fusion implants. The material used to construct the containment or channeling device may be porous, semi-porous, non-porous, bio-resorbable, or non-resorbable, depending on the therapeutic objective. The material may also be made from a continuous material with uniform properties, a fenestrated material, or a material having a variable thickness to achieve specified geometric deployment. The containment device may have many shapes depending on the structure to be treated and the intended

therapeutic effect. These include, but are not limited to, a “pouch” that can be sealed, a “stent” to channel or direct the therapeutic material, an elongated “sausage”-like shape, or a flattened “disk”-like shape. In addition, a particular embodiment may include a double- (or multiple) nested containment device, where there is at least one containment device nested within another. The containment device may be filled with a variety of therapeutic agents, depending on the therapeutic objective. In the case of VCFs, the containment device may preferably be filled with a bone cement, such as PMMA or the like, or an osteoconductive or osteoinductive material. In the case of tumors, whether in bones or soft tissue, chemotherapeutic agents may be injected into the containment device.

In a vertebroplasty operation, the containment or channeling device is inserted into the interior of the vertebral or other bony body through a hole in the exterior of the bone. The device is then deployed into the interior of the structure and filled with the desired therapeutic material. The device can be deployed by a variety of mechanisms, including response to temperature change, mechanical mechanisms, or deployment by a suitable gas. Alternatively, the containment or channeling device may be self-expanding, assuming its secondary shape automatically upon release from the delivery device. In the case of a VCF, the therapeutic material utilized is often PMMA or some other bone cement. The device can then be sealed, using a variety of methods, if desired.

Depending on the therapeutic objective, the containment or channeling device can be accessorized accordingly. The device may be made detachable where permanent implantation is desired. A wide variety of detachment technologies are known in the art. Preferably, an electrolytic detachment technology, using a braided catheter, may be used to separate the containment and delivery devices after the containment device is filled. The device may also be retrievable where only temporary implantation is needed.

In addition, the containment or channeling device may also be combined with other external or internal systems to monitor healing and/or stimulate therapeutic responses. For example, some device and environmental controls may include, but are not limited to, phototherapeutic modalities, temperature modulation, electrical stimulation, and electromagnetic fields.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the present invention are illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings, in which like reference numerals refer to like components in which:

FIG. 1A is a lateral view of three normal vertebrae;

FIG. 1B is a lateral view of three vertebrae wherein the vertebral body of the middle vertebra is compressed;

FIG. 2 is a lateral view of a compressed vertebra with bone cement extruded through the fractured vertebral vault;

FIG. 3 is a top view of a probe including a catheter tube with an expandable structure in a substantially collapsed condition attached to the distal end of the catheter;

FIG. 4A is a lateral view of a transpedicular placement of the a representative expandable containment device into a damaged vertebra;

FIG. 4B is a vertical section through a vertebral bone showing an attached containment device in a substantially collapsed condition attached to the distal end of a catheter with a severable electrolytic joint;

FIG. 5 is a top view of a lumbar vertebra, partially cut away;

FIG. 6A is a lateral view of one posterior access route to the anterior vertebral body shown in FIG. 1;

FIG. 6B is a top view of transpedicular and parapedicular routes to the anterior vertebral body; and

FIG. 7A is a side-view of a self-expanding containment device;

FIG. 7B is a side-view of the self-expanding containment device being deformed by a ball valve actuator; and

FIG. 7C is a side-view of the self-expanding containment device deformed by the ball valve actuator to assume a concave shape.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning to FIG. 1A, the lateral view of typical spinal motion segments are depicted, with lumbar vertebrae 22, 26, and 28. In contrast, FIG. 1B illustrates a lateral view of a segment of a spinal column in which the middle vertebra 26' is compressed. Compression can result from conditions such as osteoporotic fractures, malignant metastatic disease, and benign tumors of the bone and are suitable for treatment using the present invention.

The percutaneous injection of bone cements, such as PMMA or the like, in vertebroplasty and kyphoplasty procedures has had some success in the treatment of pain associated with VCFs commonly found in osteoporosis patients. The bone cement is believed to solidify the porous inside and/or potential fractures on the outside of the vertebral body. When effectively injected, the bone cement is thought to prevent painful motion of the bony

segments and to strengthen the spinal column to prevent further degradation and collapse. Leakage of the bone cement outside of the preferred treatment zone, however, not only does not alleviate the pain but can also lead to serious side effects. As seen in FIG. 2, where bone cement has extruded through the fractured vertebral vault 30, an exposed, sharp, abrasive, and durable surface 32 may be formed. This extruded media could erode nearby anatomic structures, causing further pain and complications. The precise direction, placement, and containment of therapeutic media and agents is fundamental to optimal patient outcomes. Iatrogenic injury may be reduced or eliminated by the proper application of a containment or channeling technology. The present invention tends to prevent the unintentional migration of implanted materials, such as bone cement, from the treatment site. This invention, however, is not limited to the treatment of fractures in the vertebra. The containment device may be utilized in any other bone or soft tissue where it is desired to control either the release or the unintentional migration of a therapeutic agent. Moreover, it may be utilized to concentrate therapeutic agents at the treatment site, resulting in their improved biomechanical function and/or therapeutic effect.

1. THE DEVICE

The containment or channeling device of the present invention is a generally hollow or fillable body that concentrates the focus of the therapeutic agent and reduces or prevents unintentional migration of therapeutic materials from the interior of the containment or channeling device into tissues or voids that are intended to be preserved. As depicted in FIG. 3, one embodiment of the device 84 includes a fillable or expandable body 85 made from a relatively soft, flexible material. The shape of the device will depend upon the therapeutic objectives surrounding its use and the conformity tolerances of the tissues being treated. In many cases, where the wall of the containment or channeling device is made from a relatively soft, flexible material, such as a fabric or a membrane, the containment device 84 could conform to the cavity inside of the vertebral or other bony body or soft tissue being treated. Alternatively, the device may be made of a semi-compliant or rigid material having a pre-determined shape. The containment or channeling material may be porous, semi-porous, non-porous, bioresorbable, or non-resorbable. It may be made from a continuous material with uniform properties or it may be interrupted or fenestrated to achieve the treatment objectives. In some instances the materials may have a variable thickness or durometer (hardness) to achieve specialized geometric deployment. For example, a device material may be produced to allow geometric locating or anchoring protrusions from nominal surfaces of the containment device. In addition, self-expanding devices that rely on the design and

biomaterial state of the art may be beneficial in some instances. The specialized properties of memory metals, memory polymers, and other suitable materials may contribute to the deployment and/or shaping of such a containment or channeling device.

Depending on the tissue to be treated and the intended therapeutic effect, the containment or channeling device may be many different shapes. Some embodiments may serve a directional or containment function by directing, channeling, or concentrating the treatment media within a specific anatomic orientation or structure or into a target treatment area. In such a case, the self-expanding device may be closed like a “pouch” that can be sealed after filling or open like a “stent” to channel the material more precisely.

One particular embodiment may self-expand, similar to a stent, and assume the geometry of a curved column (similar to a sausage casing or linked sausage casings), with either a closed or open end, that could serve to capture and/or channel the therapeutic media to achieve an optimal medical outcome. For example, the physician could carve out a curved void in the anterior region of the vertebral body and then deploy the elongated, curved device into the cavity. Where the device has at least one open end, e.g., similar to a curved hollow tube, the therapeutic media would leak out the open ends of the device, coming into contact with the cancellous bone along the lateral edges of the vertebral body. Although the therapeutic media, e.g., bone cement, would subsequently invade the interstices of the cancellous bone, the containment channel would still serve its intended purpose by preventing the bone cement from entering the venous plexus.

In another embodiment, as seen in FIG. 7A, the containment or channeling device 120 may have a bulbous geometry that could be manipulated to assume alternative shapes as it conforms to the anatomy where it is inserted. During or after deployment of the device, application of an external force could cause the containment device, which may comprise memory metals or memory polymers, to deform plastically into the shape or space of the tissues that are to be treated. For example, as depicted in FIG. 7C, after filling with the therapeutic material, the containment device 120 may be collapsed to assume a concave disk-like geometry 120'.

Another desirable embodiment may be a double (or multiple nested) containment device where there are at least two devices, nested within each other. In this embodiment, one containment device would surround the other and each would be capable of being filled with a therapeutic agent. For example, in the treatment of a soft tissue lesion (e.g., tumor, etc.), it may be beneficial to have an inner containment device with a structural material to provide load bearing support, while filling the outer containment device with a chemotherapeutic

agent. In this manner, as the lesion responds to chemotherapeutic agent and “shrinks,” the structural material could remain intact to support the tissue that remains.

Many different delivery devices may be used in conjunction with the containment or channeling device, enabling the placement of the containment device in the proper treatment site. These include, but are not limited to, a catheter, cannula, needle, syringe, or other expandable delivery device. For example, one embodiment of the invention, as shown in FIG. 3, includes a catheter 78 having a proximal end 80 and a distal end 82. A proximal end 86 of a flexible containment device 84 is attached to the distal end 82 of the catheter 78 in an appropriate manner, e.g., cyanoacrylate glue (or other appropriate adhesive) or construct welded joints (metallic and non-metallic), that may best serve any desirable detachment system. These detachment systems include any joint severable by electrolytic, mechanical, hydraulic, photolytic, thermal, or chemical means.

A wide range of materials can be placed into or, alternatively, coated onto the outside of the containment or channeling device. Bone cement, such as PMMA or the like, could be injected into the containment device 84 to treat compression fractures in the vertebral bodies. Likewise, any number of polymer or liquid formulas, properly contained or channeled, may serve the therapeutic requirements equally well. The biomaterial need only be adapted to physiology, which is primarily its viscoelastic and strength requirements, suited to the fit, form, and function of the treated structures and clinical outcome requirements. Where the wall of the containment or channeling device is formed from a non-porous material, the device could prevent the material, e.g., PMMA or epoxy, from “leaking” outside of the vertebra. In the alternative, if the wall is formed from a porous material, either rigid or flexible, the implanted materials may migrate or diffuse away from the containment device into the surrounding area. For example, where the containment device contains large pores, it may be filled with bone cement, such as PMMA or the like, possibly under pressure, until the device reaches its maximum capacity. The bone cement may then begin to seep out of the pores to form protrusions in the form of bumps or rods of bone cement extruding in an unorganized manner from the containment device. In addition to filling any remaining voids in the cancellous bone of the vertebral body, the extruded spikes may aid in anchoring the containment device in its proper therapeutic place, even if the vertebral body later changes shape due to further deterioration. In light of the progressive deterioration of bones seen in diseases such as osteoporosis and cancer, these extruded rods could provide much needed continued support even after the bone resorbs.

In addition to bone cements, other therapeutic materials may also be injected into the containment device. Where the containment device is made from porous or semi-porous materials, the therapeutic agents may escape or diffuse through the pores into the surrounding environment. The appropriate degree of porosity or permeability could be determined in order to achieve the correct dosing and may depend in part on the concentration of the therapeutic agent and the size of the treatment site. Similarly, the containment device may serve as a time-release or dosing vessel in delivering the therapeutic agent where a bio-resorbable material, such as poly-lactic acid (PLA), is used. In the treatment of fractures, osteoconductive materials, which provide scaffolds on which new bones can grow, and osteoinductive materials, which activate stem cells to promote and/or induce bone formation, would be useful in treating compression fractures and enhancing bone growth. Possible therapeutic materials to be placed in the containment device include, but are not limited to, bone cements and other autogenous tissues or cells, donor tissues or cells, bone substitutes, bone morphogenic proteins (e.g., BMP-2 or OP-1), growth factors (e.g., TGF- β , IGF I, IGF II, and platelet-derived growth factor), tissue sealants, chemotherapeutic agents, and other pharmaceutical agents.

Depending on the patient's condition, the physician may choose to modify or accessorize the containment or channeling device as needed. For example, the device may be permanently or temporarily implanted. FIGS. 4A and 4B depict the device 90 inserted through a hole 67 in the cortical bone 66 of a lumbar vertebra 50. Where the device 90 is to be implanted in the patient permanently, various detachment technologies may be employed after the containment or channeling device and therapeutic agents are delivered to the proper treatment site. Alternative detachment means may include, but are not limited to, electrolytic detachment; mechanical interference fit (Morse-taper-type, and the like) that can be detached by hydraulic technologies, ball valves, gas pressure changes; breakaway designs (severable by force or exposure to an alternate internal or external technology); photolytic means (severable by exposure to light, laser, and the like); thermal modulation (heat, cold, and radio frequency); mechanical means (screwing/unscrewing); and bioresorbable technologies (severable by exposure to an aqueous solution such as water, saline, and the like).

In one embodiment, the containment or channeling device 90 could be detached from delivery device 96 using a mechanical interference fit that can be detached by hydraulic technologies. For instance, a pressure could be applied by means of a syringe to a mechanically (friction) locked mandrel inside a tube, which is filled with a mechanically

compatible liquid. The tube could extend from the detachment area to the proximal end of the containment or channeling device 90.

In another embodiment, the containment or channeling device 90 could be detached using thermal or photolytic means. A heat or light source at the detachment area could be in
5 contact with the material connecting the proximal end of the containment or channeling device 90 and the delivery device, melting it to the point of disconnecting the containment or channeling device 90. Examples of heat or light sources include, but are not limited to, a current through a resistance wire, a laser provided through fiber optic means, or the like.

In another embodiment, the containment or channeling device 90 could be detached
10 through mechanical means. This could include various designs of interlocking ends that are held together by a sleeve. Different types of mechanically deployable joints that may be adapted for use with the containment or channeling device 90 are described in U.S. Patent Nos. 5,234,437; 5,250,071; 5,261,916; 5,304,195; 5,312,415; and 5,350,397, the entirety of which are herein expressly incorporated by reference.

In yet another embodiment, the containment or channeling device 90 could be detached
15 from a delivery device 96, such as a braided catheter, that is electrolytically conductive. The use of electrolytically detachable joints, attached to solid or braided (plurality of filaments) pusher wires, hypotubes, or braided catheters may increase physician control during insertion, navigation, deployment, detachment, and retrieval. As seen in FIG. 4B, the proximal end 97
20 of the device 90 could be attached to the distal end 98 of the braided catheter 96 in an appropriate manner. For example, a cyanoacrylate glue (or other appropriate adhesive) or a construct welded joint (metallic and non-metallic), may be used to attach the containment or channeling device 90 to the distal end 98 of the braided catheter. In general, the entirety of the braided catheter 96 is coated with an insulating material 102 from its proximal end 100
25 continuously to the electrolytically severable junction 104. Insulating material may include, but is not limited to, polytetrafluoroethylene (e.g., Teflon), polyparaxylene (e.g., parylene), or polyethyleneterephthalate (PET), polybutyleneterephthalate (PBT), cyanoacrylate adhesives, or other suitable insulating layers. The electrolytically severable junction 104, devoid of insulating material, is therefore much more susceptible to electrolysis in an ionic
30 solution such as blood or most other bodily fluids. The proximal end 100 of the braided catheter 96 may also be left bare so that a power supply 104 may be attached, which may provide power for electrolysis of the joint. The other pole of the power supply is typically attached to a patch on the skin 108 to complete the circuit. After the containment or channeling device is placed in the treatment area and filled with a therapeutic agent, the

device may be severed from the braided catheter used in delivery by the application of a small electrical current to the braided catheter 96.

When necessary, many different methods may be used to seal the containment device. In one embodiment, the containment device may contain a self-sealing one-way valve. In another embodiment, a plug, such as a detachable silicone balloon, may be used to seal the neck of the containment device. In the case of the electrolytic detachment using the braided catheter, for example, a detachable silicone balloon may be used to plug the catheter distal of the severable joint and proximal to the containment device. In yet another embodiment, the containment device may adhere to itself where it is made from a material with appropriate adhesive and/or elastic properties, thereby sealing the contents inside. In addition, where a bone cement such as PMMA or the like, or a similar substance that solidifies over time, is impregnated in the containment device, the hardening of the bone cement within the containment device after sufficient time has passed obviates the need for an additional seal. These examples of sealants are not meant to be limiting; any other sealant method known to those who are skilled in the art may be employed to close the containment device and prevent the unintentional migration of its contents from the treatment site.

Where the device or a portion of the device is only intended to be implanted temporarily, the device may be collapsed and subsequently removed from the body after the contents of the containment device have substantially migrated outside of the device or when it is desired. In order to facilitate navigation, detachment, removal, and implantation of the containment or channeling device, all or portions of the surfaces of the access, delivery, and containment devices may be modified. Surface modifications and methods may include, but not be limited to, ion bombardment, physical vapor deposition plasma coatings, water-soluble neuroprotectant or vascular protectant coatings (heparin, etc.), hydrophilic coatings, anti-adhesion coatings, peptide coatings, gene therapy treatments, anti-corrosion coatings, electrically insulating coatings, or other technologies as known in the art. These coatings may prevent further injury to the patient while the device is being removed since the coating may decrease the risk of scar tissue forming around the implanted foreign devices. As is well-known to one skilled in the art, any number of surface modifications may complement the utility of the device applications and outcomes. In addition, retrievable containment or channeling devices may utilize different delivery systems than those used in the case of detachable devices. In particular, catheters capable of electrolytic detachment may not be chosen in order to avoid the possibility of accidental detachment due to unintentional exposure of the electrolytic joint to an ionic environment.

In alternative embodiments, additional materials that enhance the delivery and therapeutic effect of the agents may also be impregnated in the containment device. These include, but are not limited to, hydrogels, hydrophilic coatings, anti-adhesion media, peptides, and genes. For example, proteins such as BMP and TGF- β are known to enhance fracture healing, but have short biological half-lives. Therefore, maintaining these proteins at the fracture site in therapeutic concentrations has been problematic in the past. Delivering genes encoding for a given growth factor in a controlled manner to the fracture site may help overcome this problem. Through the use of a porous, semi-porous, or bio-resorbable containment devices, the genes encoding for BMP or TGF- β could be released into the treatment site and taken up by recipient cells that might then produce the growth factor at the fracture site; protein concentrations may then be able to be maintained for an extended period of time.

The containment or channeling device may also be combined with device or environmental stimulation to provoke or achieve the desired deployment effect and therapeutic response. For example, some device and environmental controls may include, but not be limited to, phototherapeutic modalities, temperature modulation, electrical stimulation, and electro magnetic fields. For example, where a magnet is implanted in the containment device, application of a magnetic field may cause the implant to oscillate or may attract a magnetic media to fill the containment device. Under appropriate conditions, this micromotion may induce current to flow through the implant, ultimately resulting in enhanced bone growth and/or pain reduction. In an alternative embodiment, the containment device may be filled or coated with an electroconductive material associated with a power supply. When combined with an external controlling device to communicate with the power supply, the resulting current may enhance bone growth or other desirable tissue responses.

2. METHODS OF USE

Although, as noted above, use of the containment or channeling device of the present invention is not limited to treatment of vertebral ailments, such procedures are discussed here for exemplary purposes. Before discussing such methods of operation, various portions of the vertebra are briefly discussed. FIG. 5 depicts a top view of a vertebra 50. At the posterior of the vertebra are a right and left transverse process 52R, 52L, a right and left superior articular process 54R, 54L, and a spinous process 56. The right and left lamina, 58R, 58L, lie in between the spinous process 56 and the superior articular processes 54R, 54L, respectively. A right and left pedicle, 60R, 60L, are positioned anterior to the right and left transverse process, 52R, 52L. A vertebral arch 61 extends between the pedicles 60 and

through the lamina 58. A vertebral body 62 is located at the anterior of the vertebra 50 and joins the vertebral arch 61 at the pedicles 60. The vertebral body 62 includes an interior volume of reticulated, cancellous bone 64 enclosed by a compact, cortical bone 66 around the exterior. The vertebral arch 61 and body 62 make up the spinal canal, i.e., the vertebral
5 foramen 68; the opening through which the spinal cord and epidural veins pass.

As shown in FIGS. 4A and 4B, the present invention includes a detachable containment device 90 mounted on a delivery device 96 that is used to position, deploy, and fill the containment device 90. The physician can choose from a variety of approaches to insert the containment device into the vertebral body. As depicted in FIG. 6A, in the transpedicular
10 approach 68, access to the cancellous bone 64 in the vertebral body 62 is gained through the pedicle 60. Alternatively, as depicted in FIG. 6B, a parapedicular approach 72 may be used in which access is gained through the side of the vertebral body 62 beside the pedicle 60. This approach may especially be chosen if the compression fracture has resulted in collapse of the vertebral body below the plane of the pedicle. Still other physicians may opt for an
15 intercostal approach through the ribs (not shown) or a more clinically challenging anterior approach (not shown) to the vertebral body.

The method of the present invention further includes gaining access to the interior of the vertebral body 62 through a naturally occurring bore or passage 67 in the vertebra formed as a result of the condition to be treated, as seen in FIG. 4B. Alternatively, a bore or passage 67
20 in the bone may be formed with a drill. In the case of a flexible containment or channeling device 90, the size of the bore or passage 67 into the interior of the vertebral body 62 should be slightly larger than the external diameter of the implant body in its relaxed or pre-deployed state so that the containment device can be inserted through the bore into the vertebral body 62. Alternatively, where the containment or channeling device 90 is made from a semi-
25 compliant rigid material, the size of the bore or passage 67 must be slightly larger than the size of the external diameter of the semi-compliant or rigid implant. Depending on the level of deterioration of the vertebral body 62, the depth of the bore or passage 67 may also need to be sufficient to allow for the insertion of the full axial length of the device 90 into the vertebral body 62. In addition, the physician may further create a cavity 69 within the
30 vertebral body 62 before insertion of the device 90 if desired. This may be accomplished using any surgical tool to carve out a cavity or perhaps by using an additional expandable or deployable device, such as those used in angioplasty or atraumatic tissue expansion or dissection. The containment device is preferably placed in the center of the vertebral body

void or vault 62 in order to distribute support evenly to the entire structure and to the physiological loads typical a living organism.

As discussed before, the containment or channeling device may be delivered to the treatment site using many different delivery devices including, but not limited to, a catheter, cannula, needle, syringe, or other expandable delivery device. In one embodiment, the containment or channeling device 90 may be delivered to the treatment site via a guide sheath (not shown) through which the braided catheter 96 with the attached flexible containment or channeling device 90 in a substantially collapsed condition, may be pushed through the guide sheath to the interior of the bony body, the guide sheath having been combined with an obturator or the like, and tunneled through intervening tissue to gain access to the treatment site. The guide sheath may be retracted towards its proximal end, thereby releasing the device 90 into the interior of the vertebral body or other treatment site. Many delivery devices and methods could be employed to deliver the containment device to the treatment site and are well known to those who are skilled in the art.

Once the containment device 90 is placed in the proper treatment area, it can be filled or deployed in many ways. In one embodiment, wherein the device 90 is made from a flexible material, the device 90 may be deployed first in response to temperature change, mechanical release into the tissues, or with a suitable gas, such as carbon dioxide, and subsequently be filled with the desired therapeutic agent. For example, where a semi-porous material is used, carbon dioxide at an appropriate pressure may deploy the containment device 90, possibly creating a cavity within the cancellous bone, depending on the degree of deterioration of the vertebral body and the gas pressure used to deploy the containment device 90. The gas may subsequently escape through the pores prior to or while the containment device 90 is filled with the therapeutic material. The device 90 may also be deployed using any appropriate mechanical mechanism. This mechanical mechanism may be such that the containment device 90 may displace portions of the cancellous bone within the vertebral body upon deployment to create a cavity before it is filled with therapeutic materials. Alternatively, the device 90 could be filled directly with the therapeutic agent, possibly under pressure.

Where the containment or channeling device is self-expanding, similar to a stent, upon release from the guide sheath, the containment device may assume its primary shape within the cavity or void in which it is placed without the aid of any external forces. The device could subsequently be filled with the desired therapeutic material.

In an alternative self-expanding embodiment, the original shape of the device could be manipulated into another secondary shape with the application of an external force. As seen

in FIG. 7A, a bulbous containment device 120, which includes memory metal or memory polymer that adds to its shape, is pushed through the distal end of a delivery catheter 124, here depicted as a braided microcatheter, by a pusher wire 128. The containment device 120 contains a one-way ball valve 132 on its distal end 134, which can be sealed by the ball valve actuator 136 located on the distal end 140 of the pusher wire 128. Under image guidance, the containment device assembly 118, which includes the containment device 120, pusher wire 128, and delivery microcatheter 124, is advanced through the guide sheath (not shown). As the containment device assembly 118 exits the guide sheath (not shown), it is navigated through the tissue or tissue void to be treated. The containment device 120 is constrained in its undeployed state within the inner lumen of the braided microcatheter 124 until final anatomic positioning is achieved. The pusher wire 128 is then advanced, pushing the containment device outside of the braided delivery catheter. As seen in FIG. 7A, the containment device, which is made from a self-expanding construct including memory metals and/or memory polymers or their performance equivalent, expands into the anatomy to be treated.

FIG. 7B depicts the shaping process of the containment device 120 as the ball actuator 136 engages the dome 122 of the containment device 120. The pusher wire 128, with its ball actuator 136, is used to begin the shaping of the device by applying a retrograde motion, as if to withdraw the pusher wire 128 from the delivery microcatheter 124. As the pusher wire 128 is pulled, the ball actuator 136 engages the ball valve 132 at the distal end 134 of the dome 122 of the containment device 120. The force of this motion plastically deforms the dome 122 of the containment device 120, pulling it towards the equator 123 of the containment device 120, ultimately to reshape the containment device 120 into a concave geometry, appropriate to the anatomy to be treated. Other means to deform or shape the device include, but are not limited to, changes in temperature or the application of an electrical or magnetic field.

The net effect of this action, as seen in FIG. 7C, is to deform the armature 126 sufficient to permanently remodel the containment device 120 geometry in a manner that improves the acceptance of the biomaterial or pharmaceutical agent and ultimately the therapeutic outcomes. The dome 122 of the containment device 120 has been drawn into its base. The armature 126 has reached its plastic deformation point without compromise to the ability of the containment device to contain any therapeutic media. The remodeled shape of the containment device (disk-like or bowl-like shape) may enable the treatment of tissues that benefit from this shape alternative.

In addition, other ailments, which are not specific to bone, may also be treated with the present invention. For example, in the case of cancer, whether it be in the bone or soft tissue, placement of a containment device into or near the tumor could allow for the delivery of chemotherapeutic agents directly to the tumor. Where the containment device is made from porous, semi-porous, or bio-resorbable material, the chemotherapeutic agents contained within the containment device may be able to diffuse to the surrounding area. The containment device may be placed inside of a tumor using an appropriate interventional technique. For examples, a guide sheath may be used to tunnel through adjacent tissue. The containment device may then be inserted into the desired therapeutic site through the guide sheath. When necessary, the containment device may be attached to the soft tissue. Sutures, or other methods that are well known to those who are skilled in the art, may be used to stabilize the placement of the containment device. Possible chemotherapeutic agents include, but are not limited to, cisolatin, doxcrubicin, daunorubicin, methotrexate, taxol, and tamoxifen. And in the case of deep wounds, the containment device may be used to deliver antibodies to the site. Additionally, it is conceivable that, myofascial pain syndrome, which is a condition of the tissues characterized by intense localized pain coming from muscles and their respective connective tissues, could also be treated. A containment device made from porous, semi-porous, or bio-resorbable material may be placed in between the muscle fascia, providing for the controlled release of muscle relaxants and other therapeutic agents that may help to treat the syndrome as the therapeutic agents diffuse away from the containment device. Plantar Fasciitis, which is an inflammation of the plantar fascia tissue at its attachment to the heel bone, could also be treated through placement of the containment device near the plantar fascia (a tough, fibrous band of connective tissue that extends over the sole of the foot). Similar to the above examples, the containment device may provide for the controlled delivery of anti-inflammatory drugs and other therapeutic agents that may provide relief from the acute pain associated with the condition.

While the invention is susceptible to various modifications and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is to cover all modifications, equivalents, and alternatives falling within the scope of the appended claims.

What is claimed:

1. A medical containment device for use in a bony body, comprising:
a generally hollow body conformable to an interior cavity of a bony body having an opening through which a therapeutic material may be inserted, the generally hollow body
5 providing a barrier preventing the unintentional migration of the therapeutic material from the interior of the generally hollow body; and
a delivery device configured to convey the generally hollow body into an interior of a bony body through an opening in the bony body, wherein the generally hollow body is attached to a distal end of the delivery device.
- 10 2. The medical device of claim 1, wherein the generally hollow body is made from a flexible or conformable material.
3. The medical device of claims 1 or 2, wherein the generally hollow body is made from a porous material.
4. The medical device of any of claims 1-3, wherein the generally hollow body is made
15 from a bio-resorbable material.
5. The medical device of any of claims 1-4, wherein the generally hollow body is made from a continuous material with uniform properties.
6. The medical device of any of claims 1-5, wherein the generally hollow body is self-expandable.
- 20 7. The medical device of claim 6, wherein the generally hollow body comprises a memory metal or memory polymer.
8. The medical device of any of claims 1-7, wherein the generally hollow body has a concave shape.
9. The medical device of any of claims 1-7, wherein the generally hollow body has a
25 pouch shape.
10. The medical device of any of claims 1-7, wherein the generally hollow body has an elongate shape with at least one open end.
11. The medical device of any of the above claims 1-10, wherein the generally hollow
body is configured to carry a therapeutic material.
- 30 12. The medical device of claim 11, wherein the therapeutic material comprise one or more of a bone cement, bone morphogenic protein or a chemotherapeutic agent.
13. The medical device of any of the above claims 1-12, wherein the generally hollow body is detachable from the delivery device.

14. The medical device of claim 13, wherein the delivery device comprises an electrolytically severable junction adapted to dissolve upon imposition of an electric current.

15. The medical device of claim 13, wherein the delivery device comprises a friction-locked junction adapted to disconnect upon imposition of an external pressure.

5 16. The medical device of claim 13, wherein the delivery device comprises a severable junction adapted to dissolve upon exposure to heat.

17. The medical device of claim 13, wherein the delivery device comprises a severable junction adapted to dissolve upon exposure to light.

10 18. The medical device of claim 13, wherein the delivery device comprises a junction of interlocking ends that is mechanically disconnectable.

19. The medical device of claim 13, wherein the delivery device comprises a severable junction adapted to dissolve upon exposure to an aqueous environment.

20. The medical device of claim 13, wherein the delivery device comprises a severable junction adapted to break upon application of an external force.

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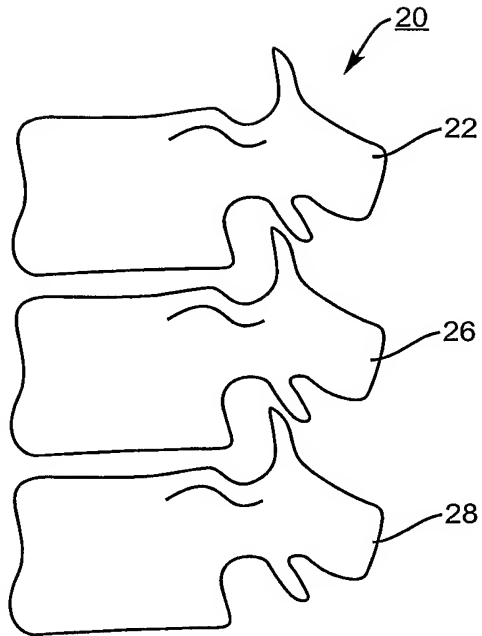


Fig. 1A

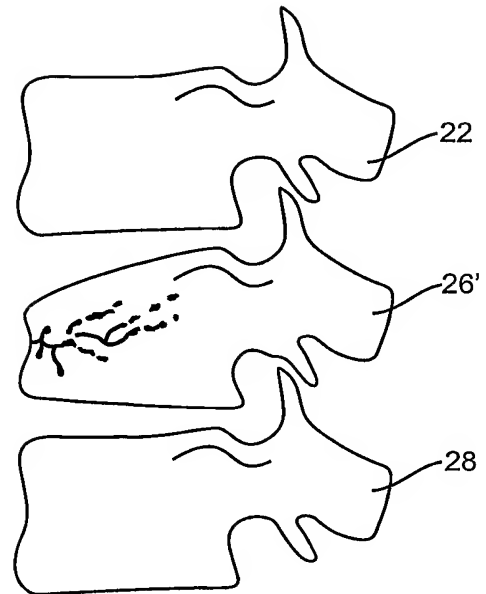


Fig. 1B

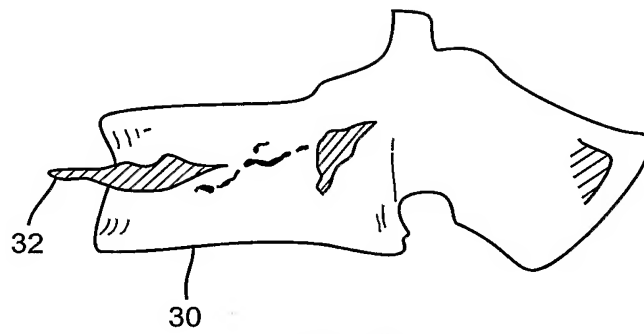


Fig. 2

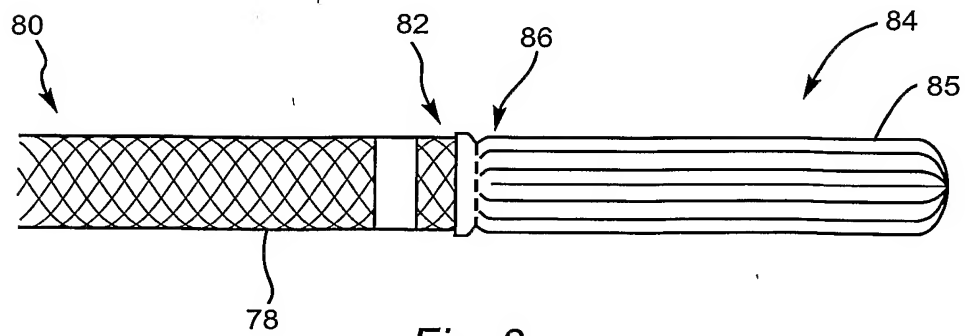


Fig. 3

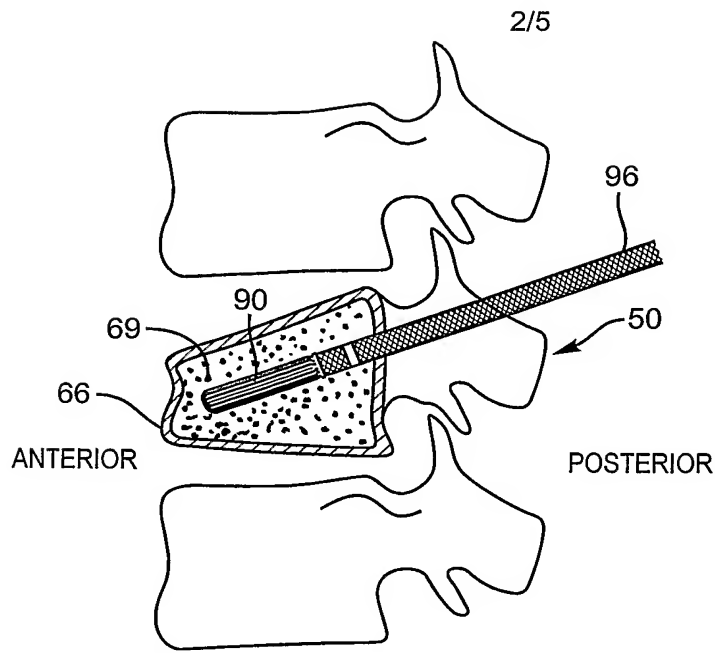


Fig. 4A

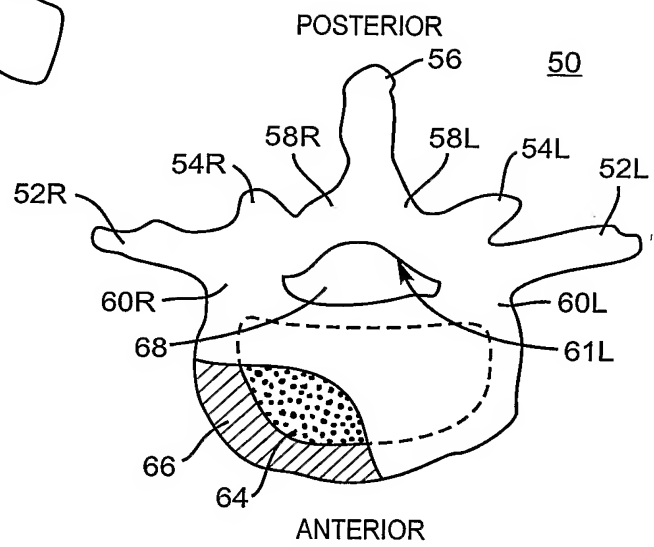


Fig. 5

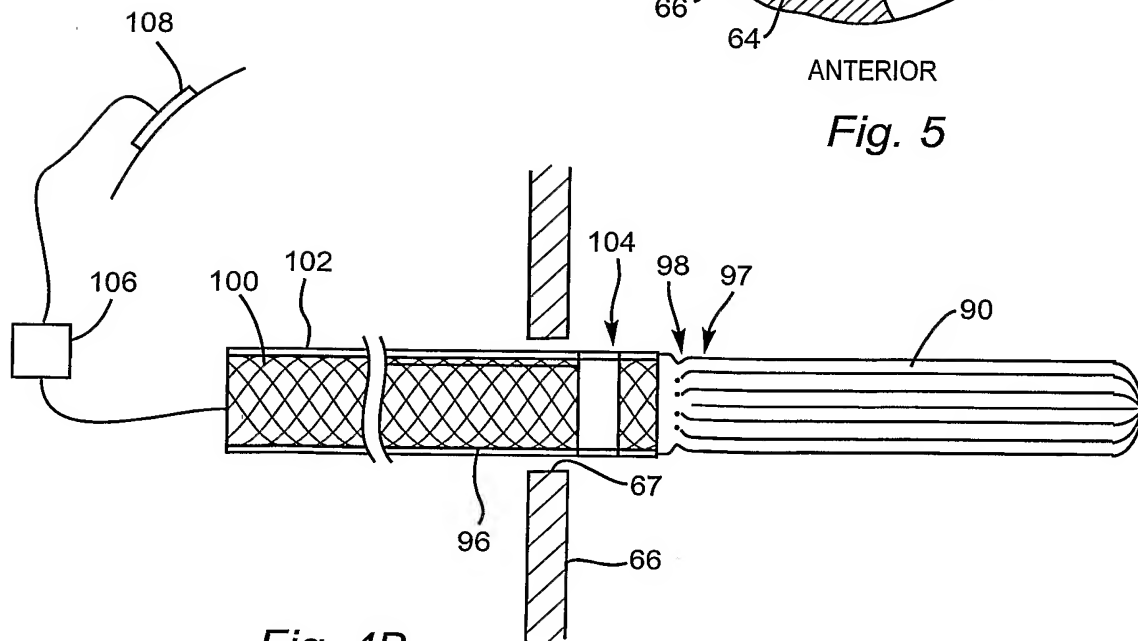


Fig. 4B

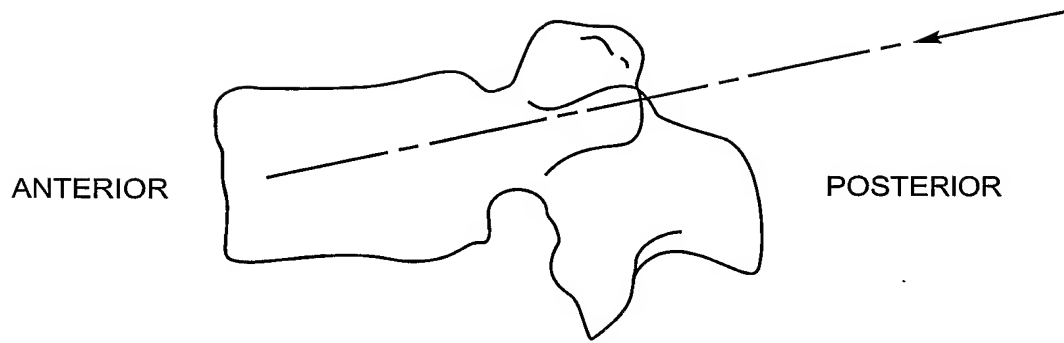


FIG. 6A

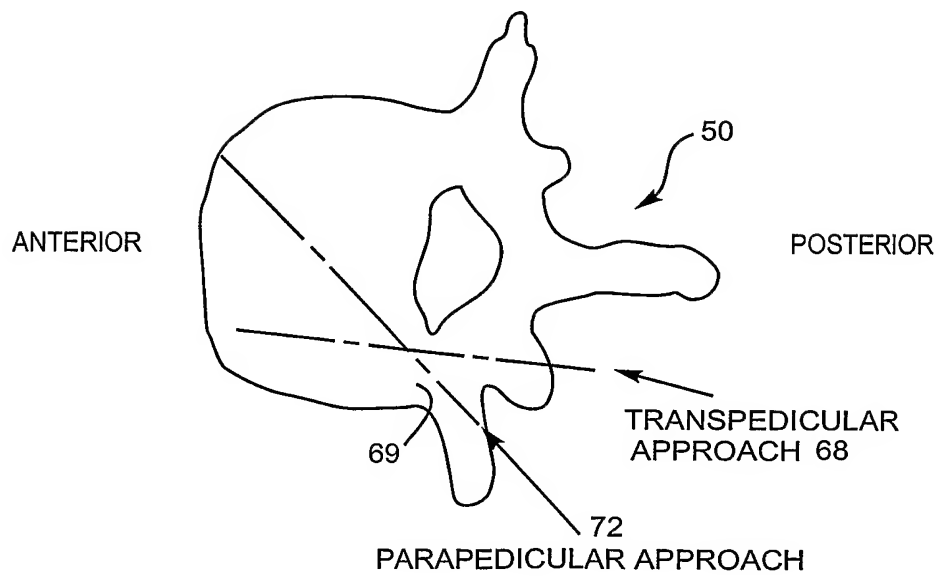
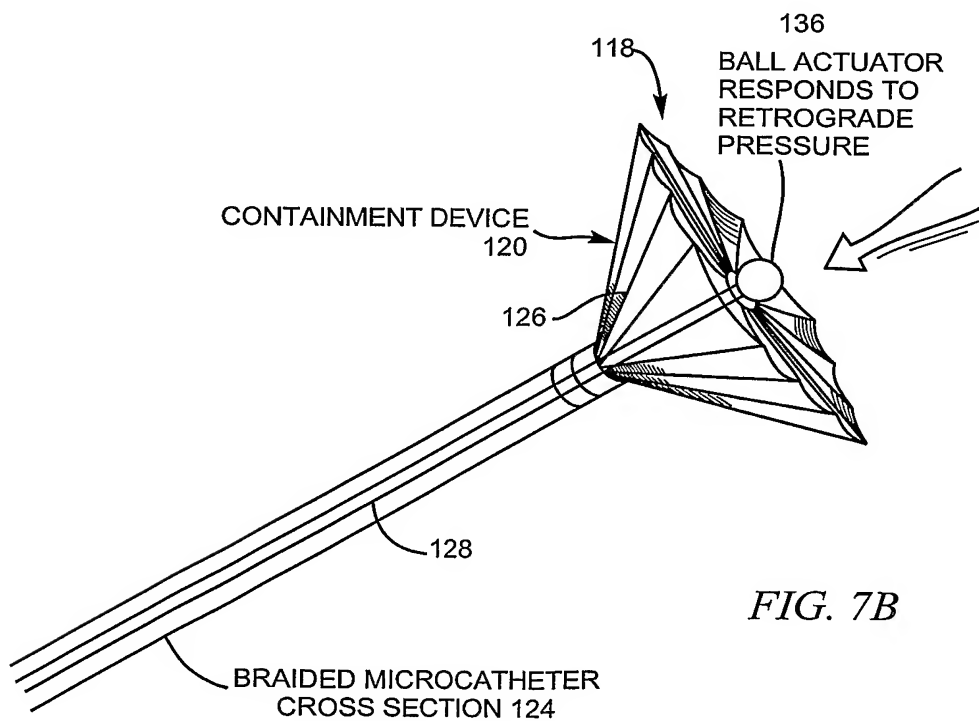
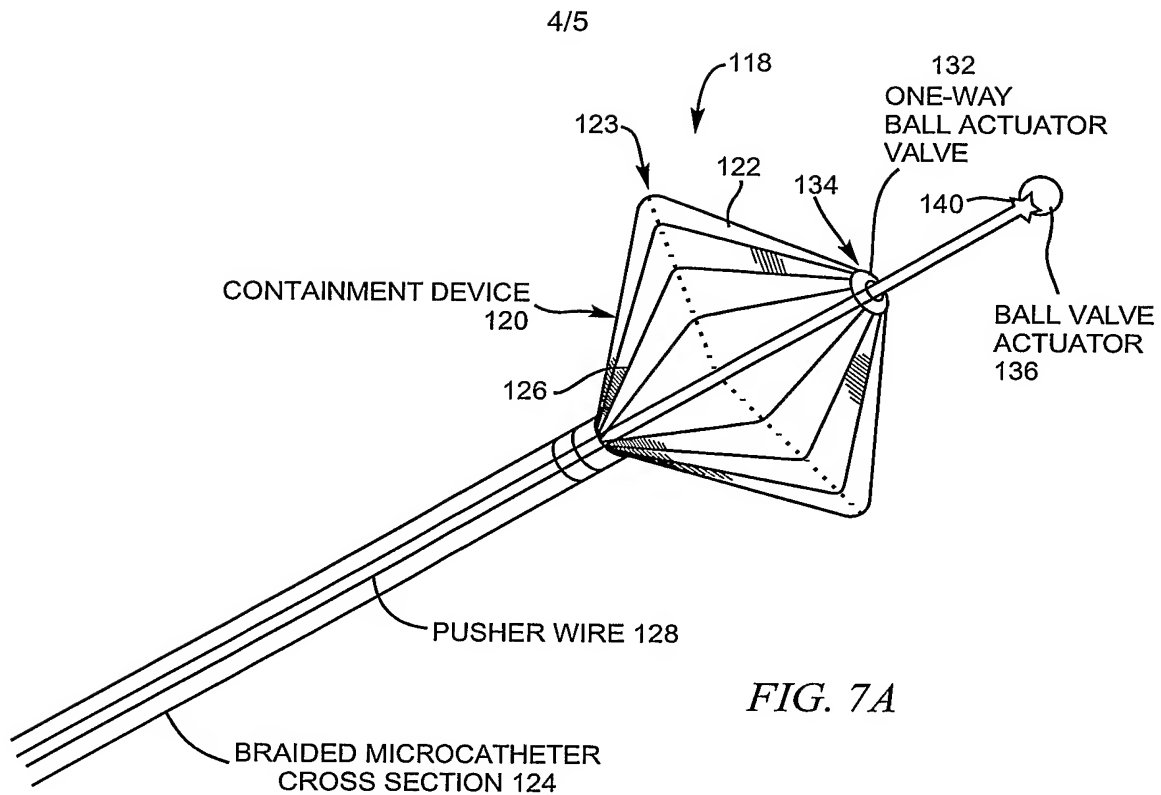
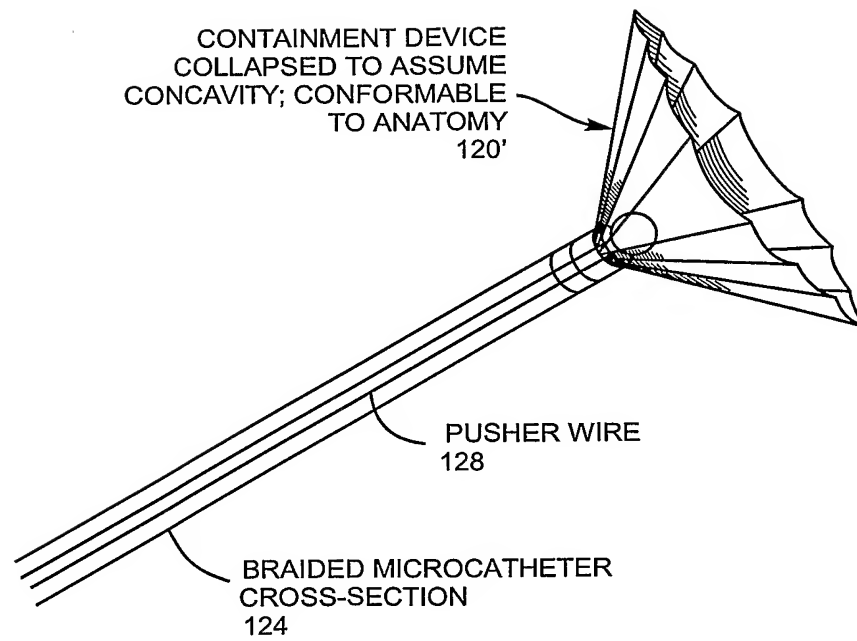


FIG. 6B



*FIG. 7C*

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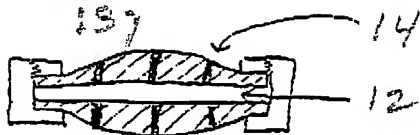
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(54) Title: PROSTHETIC COMPONENTS WITH CUSHIONING ELEMENTS



(57) Abstract: A cushioned prosthesis configured for use with a bone having an articular surface including a compressible component (12) and a force-transfer component (13) disposed between the compressive member and the articular surface of the bone.

WO 03/094806 A1

- 1 -

PROSTHETIC COMPONENTS WITH CUSHIONING ELEMENTS

FIELD OF THE INVENTION

This invention relates generally to prosthetic implants and, more particularly, to devices with cushioning elements, including springs and compressible, resilient members.

5 BACKGROUND OF THE INVENTION

Artificial disc replacements (ADRs) are frequently made of hydrogels or metal and rubber. Hydrogel ADRs generally surround the hydrogel core with a flexible constraining jacket, as shown in PCT/US00/80920, WO 00/59412.

Unfortunately, the flexibility of the hydrogel and the constraining jacket allow
10 hydrogel ADRs to change shape and extrude through defects in the annulus through which the ADR was inserted, for example. Metal and rubber ADRs often fail at the metal-rubber interface. The rubber fails with the high shear stresses or the rubber separates from the metal with shear stress.

There does exist issued patents that relate to enclosing or sealing hydrogel
15 materials. Of interest is U.S. Patent No. 6,022,376, which teaches a hydrogel enclosed by a fluid permeable bag. However, the fluid bag does little to protect the hydrogel from shear stress, and the rough texture of the bag may cause hydrogel wear from friction.

U.S. Patent No. 5,002,576 teaches an elastomer enclosed by rigid cover plates
20 and a corrugated tube. The elastomer is sealed from fluids of the body. The corrugated tube allows movement of the cover plates. The corrugated tube may reduce shear forces on the elastomer. U.S. Patent Nos. 5,865,846; 6,001,130; and 6,156,067 teach a spherical articulation between ADR EPs and an elastomer.

The elastomer may be sealed within the ADR EPs. An annular gasket may
25 reduce shear forces on the elastomer. U.S. Patent No 5,893,889 teaches an elastomer that is sealed between ADR EPs. The device uses a ball and socket feature to reduce shear on the elastomer. U.S. Patent No. 6,063,121 incorporates X-shaped wires into the '889 device to reduce rotation.

- 2 -

SUMMARY OF THE INVENTION

This invention relates generally to prosthetic implants and, more particularly, to devices with cushioning elements, including springs and compressible, resilient members.

- 5 In most embodiments, the spring(s) compressible member(s) are motion-restricted in some manner, and may be encased, encapsulated, contained, or otherwise protected with one or more rigid components associated with an articulating bone. The embodiments are applicable not only to artificial disc replacement (ADR) devices, but also to joint situations including total knee, hip arthroplasty, elbow, shoulder, wrist
10 and ankle applications.

- The compressible materials may include synthetic rubbers, hydrogels, elastomers, and other polymeric materials such as viscoelastic polymers and foam polyurethanes. In such embodiments, the invention effectively combines the advantages of such materials (cushioning, shape memory, and expansion after
15 insertion in the case of hydrogels), while providing increased protection, particularly the elimination of shear stresses. When applied to an ADR, the invention also minimizes the risk of extrusion.

- A force-transfer component of some kind is used to couple the compressible member to an articular bone surface, and a container may surround the cushioning
20 element to perform functions such as:

- A. Holds the cushion in place.
- B. Reduces frictional forces on the cushion element.
- C. Reduces shear forces on the cushion element.
- D. In some embodiments, seals the cushion element from exposure to the
25 fluids of the body. Body fluids may destroy the cushion element.
- E. In some embodiments, retains particle debris.
- F. Prevents the ingrowth of tissues that could inhibit motion.

BRIEF DESCRIPTION OF THE DRAWINGS

- FIGURE 1A is a side view of a contained artificial disc replacement (ADR) of
30 the present invention;

FIGURE 1B shows the cross-section of the device of Figure 1A;

- 3 -

FIGURE 1C is an exploded view of the device of Figures 1A and 1B;

FIGURE 1D is a top view of Figures 1A-1C in position between a pair of adjacent vertebrae;

FIGURE 1E shows the device in a dehydrated state;

5 FIGURE 1F shows the device in a hydrated/expanded state;

FIGURE 2A shows an ADR according to the present invention disposed symmetrically between adjacent vertebrae;

FIGURE 2B illustrates an asymmetrical configuration;

10 FIGURE 3A illustrates a device dehydrated for insertion between the vertebrae;

FIGURE 3B illustrates the device expanded after insertion and hydration;

FIGURE 4A shows the device of the present invention with endplates in position;

FIGURE 4B is a cross-section of Figure 4A;

15 FIGURE 5A is a simplified side view of an alternative embodiment of an ADR;

FIGURE 5B shows a cross-section of the more encapsulated device showing channels for facilitate fluid transfer;

FIGURE 5C is a cross-section showing the hydrogel in a desiccated state;

20 FIGURE 5D is a cross-section showing the hydrogel in a hydrated, expanded form;

FIGURE 5E shows the side view of the device in place between upper and lower vertebrae;

FIGURE 5F is an anterior-posterior view of the device in place;

25 FIGURE 6A is a side-view of the device of Figure 5A with inferior and superior end plates attached to the respective vertebrae;

FIGURE 6B is an anterior-posterior view of the device of Figure 6A in position;

30 FIGURE 7A is an anterior-posterior view of in partial cross-section of an ADR incorporating multiple cylinders;

FIGURE 7B is a side-view, also in partial cross-section;

FIGURE 7C is an axial cross-section of a device containing a central guide cylinder surrounding six pistons;

- 4 -

FIGURE 7D shows two embodiments with multiple cylinders;

FIGURE 8A is a coronal/sagittal cross-section of the cylinders according to the present invention;

FIGURE 8B is an illustration of two vertebrae in extension;

5 FIGURE 9 shows an embodiment with the peg projecting from the posterior aspect of the inferior surface of the upper plate;

FIGURE 10A shows a further alternative embodiment of the present invention;

FIGURE 10B is a frontal view in cross-section showing partial cushioning;

10 FIGURE 10C is a frontal cross-sectional view illustrating full cushioning;

FIGURE 11A is a top-down view of an embodiment showing opposing retaining cylinders on either side of a central resilient member;

FIGURE 11B is a side-view drawing in cross-section showing partial cushioning of the device of Figure 11A;

15 FIGURE 11C is a side-view drawing in partial cross-section illustrating the embodiment of Figures 11A and 11B;

FIGURE 12A shows an anterior-posterior view of the embodiment of the invention wherein the end plates of ADR may contain hollow keels on the vertebral side;

20 FIGURE 12B is a lateral view of Figure 12A;

FIGURE 12C is a top-down view illustrating the bone ingrowth area of Figure 12A;

FIGURE 13 is a cross-section of an embodiment with multiple pistons connected to the top plate via a rod;

25 FIGURE 14A is a cross-section illustrating an anterior-posterior view of two pedicle screws;

FIGURE 14B is a cross-sectional lateral view of the embodiment of Figure 14A;

30 FIGURE 15A is a side-view of a pedicle screw having an axle to receive a shock absorber according to the present invention;

FIGURE 15B is a close-up of the shock absorber mechanism associated with a pedicle screw embodiment of Figure 15A;

FIGURE 16 is a cross-sectional view of a tibial component according to the present invention;

FIGURE 17 is a drawing which shows how a locking component may be incorporated in the design;

5 FIGURE 18 is a side-view cross-section of a tibial component for a knee replacement;

FIGURE 19 is a side-view drawing of an embodiment illustrating the way in which the invention may be applied to the hip;

10 FIGURE 20 is a sagittal cross section of the spine and a single cylinder embodiment of the ADR shown in Figure 7;

FIGURE 21A is a sagittal cross section of an alternative embodiment of the ADR;

FIGURE 21B is a sagittal cross section through another embodiment of the ADR shown in Figure 21A;

15 FIGURE 22 is a sagittal cross section of an alternative embodiment of the ADR shown in Figure 5A;

FIGURE 23A is a sagittal cross section through yet another embodiment of the ADR of the present invention;

20 FIGURE 23B is a sagittal cross section of the embodiment of the ADR shown in Figure 23A;

FIGURE 23C is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 23B;

FIGURE 24A is a sagittal cross section through another embodiment of the ADR;

25 FIGURE 24B is a coronal cross section through the ADR drawn in Figure 24A;

FIGURE 25 is a lateral view of the spine and a multi-component embodiment of the ADR drawn in Figure 2A;

30 FIGURE 26 is a sagittal cross section through the embodiment of the ADR drawn in Figure 5A;

FIGURE 27 is a view of the top of an alternative embodiment of the ADR drawn in Figure 11A;

- 6 -

FIGURE 28A is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 13;

FIGURE 28B is a coronal cross section of the embodiment of the ADR drawn in Figure 28A;

5 FIGURE 29A is a coronal cross section of a constrained embodiment of the ADR shown in Figure 11;

FIGURE 29B is an exploded anterior view of the ADR shown in Figure 29A;

FIGURE 30 is a sagittal cross section of an alternative embodiment of the ADR shown in Figure 11;

10 FIGURE 31 is a sagittal cross section of an alternative embodiment of the ADR drawn in Figure 22;

FIGURE 32 is a lateral view of an alternative embodiment of the ADR drawn in Figure 21A;

15 FIGURE 33A is a sagittal cross section of an alternative embodiment of the ADR;

FIGURE 33B is a view of the top of the elastomeric component and the socket of the inferior ADR EP drawn in Figure 33A;

FIGURE 34 is a sagittal cross section of an alternative embodiment of the ADR;

20 FIGURE 35A is a sagittal cross section of the spine and an alternative embodiment of the device;

FIGURE 35B is a sagittal cross section through another "Disc Spacer" embodiment of the ADR;

25 FIGURE 36C is a sagittal cross section through another embodiment of the device;

FIGURE 36D is a sagittal cross section through another embodiment of the device;

FIGURE 37A is a lateral view of an alternative embodiment of an ADR according to the present invention;

30 FIGURE 37B is a sagittal cross section of an embodiment of the ADR similar to that drawn in Figure 21A;

FIGURE 38 is a lateral view of an alternative embodiment of an ADR;

- 7 -

FIGURE 39 is a sagittal cross section through an alternative embodiment wherein the caps and springs are contained in cylinders;

FIGURE 40 is a lateral view of an alternative embodiment wherein the top of the spring caps are concave rather than convex;

5 FIGURE 41A is a lateral view of an alternative embodiment illustrating the use of a C-shaped spring that cooperates between convex projections from the ADR EPs;

FIGURE 41B is a sagittal cross section through the embodiment of the ADR shown in Figure 41A;

10 FIGURE 41C is a view of the top of the springs and inferior ADR EP shown in Figure 41A;

FIGURE 41D is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 41A;

15 FIGURE 41E is a sagittal cross section through the embodiment of the ADR drawn in Figure 41D;

FIGURE 42 is a lateral view of the spine and an alternative embodiment including spring caps that articulate with a vertebral endplate;

FIGURE 43A is a lateral view of an embodiment of the invention applied to total knee replacement;

20 FIGURE 43B is sagittal cross section of the embodiment of the device drawn in Figure 43A;

FIGURE 43C is a view of the bottom of upper metal component;

FIGURE 43D is a view of the bottom of an alternative embodiment of the component drawn in Figure 43C incorporating two pistons;

25 FIGURE 43E is a coronal cross section of the embodiment of the device drawn in Figure 43D;

FIGURE 44A is a sagittal cross section of an alternative embodiment;

FIGURE 44B is a view of the top of the cylinder component of the device drawn in Figure 44A;

30 FIGURE 45A is a sagittal cross section of an alternative embodiment including a different locking mechanism;

FIGURE 45B is an exploded view of the embodiment of the invention drawn in Figure 45A;

- 8 -

FIGURE 46 is a sagittal cross section through a further embodiment of the invention;

FIGURE 47 is a sagittal cross section through yet a further embodiment of the device;

5 FIGURE 48 is a sagittal cross section of an alternative embodiment of the invention including hydrogel as a cushion element;

FIGURE 49 is a sagittal cross section of an alternative embodiment of the invention wherein the cushion element is enclosed within a flexible metal component; and

10 FIGURE 50 is a sagittal cross section of another embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

This invention solves problems associated with artificial disc replacement (ADR) devices and joint-related components, including those associated with total-knee and hip replacements, through the use of compressible/resilient materials, springs, and devices for controlling motion and containing elements in need of protection, for example. In preferred embodiments, the invention effectively combines the advantages of hydrogels and other compressible/resilient materials while minimizing shear stresses. U.S. Patent Nos. 5,047,055 and 5,192,326, both incorporated by reference, list some of the applicable hydrogels. The small size of the desiccated hydrogel facilitates insertion, after which the hydrogel imbibes fluids and expands. Other non-hydrogel compressible and/or resilient materials may alternatively be used, including elastomers, shape-memory polymers, which would increase in height after they are inserted. As another example of many, non-hydrogel polymers such as acrylics may be used which change shape with a change in temperature. Thus, as used herein, the term "hydrogel" should be taken to include other resilient/compressible materials.

The hydrogels are generally protected from shear stress, thereby extending longevity. In particular, the hydrogel is contained, constrained or enclosed within a cavity or cylinder which may include one or more pistons. The hydrogel provides cushioning, while the pistons facilitate articulation either directly or indirectly with bone surfaces. Thus, the invention offers the advantages of metal-on-metal while

- 9 -

providing for cushioning. The hydrogels allow for physiologic tension adjustment since they can change size based upon imbibing fluid and the pressure on the hydrogel. As such, the hydrogel component of the device can change height to balance the forces against the surrounding tissues.

5 The cylinder and piston would likely be made of metal such as stainless steel, titanium, chrome cobalt, or other biocompatible metal or ceramic alloy. Surfaces to promote bone ingrowth could be used on the covers. The hydrogel embodiments may incorporate channels for the diffusion of fluids in and out of the cylinder. Optional permeable membranes can also be used to prevent extrusion of the hydrogel through
10 the channels. The permeable membrane traps the hydrogel but allows fluids to move freely across the membrane.

Figure 1A is a side view of a contained artificial disc replacement (ADR) according to the invention. Figure 1B is a drawing that shows cross-section of the device of Figure 1A, including a hydrogel-filled chamber 12 and container 13 with
15 channels 14 to permit fluid transfer. Container 13 is preferably rigid but may itself be semi-rigid or constructed of a material such as polyethylene to provide low-friction bearing surfaces. Figure 1C is an exploded view of the device of Figures 1A and 1B showing optional permeable membranes 16, 18. Figure 1D is a top view of Figures 1A-1C in position between a pair of adjacent vertebrae. Figure 1E shows the device
20 in a dehydrated state with the hydrogel 12' assuming a flattened form for easier insertion; Figure 1F shows the device in a hydrated/expanded state.

Devices according to the invention, regardless of disposition in the body, may be placed symmetrically or asymmetrically. Figure 2A shows an ADR according to the invention disposed symmetrically between adjacent vertebrae. Figure 2B
25 illustrates an asymmetrical configuration. Figure 3A illustrates a device dehydrated for insertion between the vertebrae and Figure 3B illustrates the device expanded after insertion and hydration. As shown in Figure 4, endplate covers 20, 21 may be provided in conjunction with the contained hydrogel ADR according to the invention. Figure 4A shows the device and endplates in position. Figure 4B is a cross-section.

30 Figure 5A is a simplified side view of an alternative ADR according to the invention, wherein the hydrogel 22 is further encapsulated. Figure 5B is a cross-section of the device showing channels 28 for facilitate fluid transfer. Again, a fluid permeable membrane 24 may be useful. Figure 5C is a cross-section of the device

- 10 -

with the hydrogel in a desiccated state. Figure 5D is a cross-section showing the hydrogel in a hydrated, expanded form. Figure 5E shows the device in place between upper and lower vertebrae from a side view. Figure 5F is an A-P of the device in place. Figure 6A is a side-view of the device of Figure 5, with inferior and superior endplates 30, 31 attached to the respective vertebrae. Figure 6B is an A-P view of the device of Figure 6A in position.

The invention may also include two or more cylinders to reduce the tendency of a single assembly to tilt when non-uniform pressure is applied. Figure 7A is an A-P view of in partial cross-section of an ADR held in place with screws such as 32 incorporating multiple cylinders. Figure 7B is a side-view, also in partial cross-section. Figure 7C is an axial cross-section of a device containing a central guide cylinder 34 surrounding six other cylinders such as 36 with a piston being depicted at 36. It will be appreciated that more or fewer guide cylinders and/or pistons may be used as shown, for example, in Figure 10.

Figure 7D shows two embodiments with multiple cylinders. In the partial cushion embodiment (upper drawing), a spherical end 40 of the peg projecting from the top plate rests against and is partially supported by a concavity 42 in the lower plate. In this and other applicable embodiments, any suitable compressible/resilient material may be used, but if the material is hydrogel, holes such as 42 may be provided for fluid transfer. In the full cushion embodiment (lower drawing), the peg projecting from the top plate fits into a restraining cylinder 44. The peg 43 from the top plate does not rest against the bottom plate in this embodiment. In either case, the end of the peg is preferably spherical to allow angular motion between the two plates. The cylinder is shown at 46.

Figure 8A is a coronal/sagittal cross-section of the cylinders according to this embodiment of the invention, showing the hydrogel at 50. The top plate preferably includes a concavity 52 opposite the piston 46. Figure 8B is an illustration of two vertebrae in extension, showing the way in which the front piston 56 is raised and the back piston 58 is lowered. Note that the peg that projects from the lower portion of the upper plate need not be central in location. Figure 9 shows an embodiment with the peg projecting from the posterior aspect of the inferior surface of the upper plate. Posterior peg placement allows a larger anterior cylinder. The larger anterior cylinder

may be better at handling the larger forces placed on the anterior portion of the disc replacement during spinal flexion.

Figure 10A is a top cross-section view of an embodiment showing multiple peripheral cylinders and additional internal hydrogel chambers 66. Among other advantages, this may help to prevent rotatory subluxation of the top component relative to the bottom component while allowing more area centrally for the hydrogels/polymer cylinders. Figure 10B is a frontal view in cross-section showing partial cushioning. Figure 10C is a frontal cross-sectional view illustrating full cushioning.

Two or more retaining cylinders may also be used to reduce the shear on the compressible/resilient material, be it a solid piece of silicone rubber, elastomer or hydrogel-type material. Figure 11A is a top-down view of an embodiment showing opposing retaining cylinders 68 on either side of a central resilient member 70. Figure 11B is a side-view drawing in cross-section showing partial cushioning of the member 70. Figure 11C is a side-view drawing in partial cross-section illustrating the embodiment of Figures 11A and 11B providing a full cushioning and reduced shear capability.

Reference is now made to Figure 12A, which is an A-P view of the embodiment of the invention wherein the end plates of ADR may contain hollow keels on the vertebral side. Figure 12B is a lateral view and, Figure 12C is a top-down view illustrating the bone ingrowth area 72. The vertebrae would be osteotomized to make room for the keels. The bone from the osteotomy sites would be morselized and placed inside the hollow keels. The morselized bone would promote ingrowth into the end plates of the ADR, much like hollow cages promote bone ingrowth.

Figure 13 is a cross-section of an embodiment with multiple pistons 74 connected to the top plate 76 via rods 78, much like the design of rods that connect pistons to a crankshaft in an engine. The shock absorber concept according to this invention may also be used with respect to vertebral shock absorbers. The compressible/resilient material, again preferably a hydrogel, is depicted at 80. Figure 14A is a cross-section illustrating an A-P view of two pedicle screws 81, 83 coupled in this way. The piston is shown at 82 and the compressible/resilient material is depicted at 84. Figure 14B is a cross-sectional lateral view of the embodiment of

- 12 -

Figure 14A. The piston is shown at 82 and the compressible/resilient material is depicted at 84.

Figure 15A is a side-view of a pedicle screw having an axle 86 to receive a shock absorber according to the invention. A holding nut is shown at 88. Figure 15B is a close-up of the shock absorber mechanism associated with a pedicle screw embodiment. The piston is shown at 90 and the compressible/resilient material is depicted at 92. An attachment is shown at 94, and a hole for coupling to a pedicle screw is shown at 96.

The cylinders could be made of ceramic, metal, or metal lined with ceramic. The pistons could also be made of metal, ceramic, alloys and so forth. In any case, the articulation of the top and bottom plates is preferably metal-to-metal or ceramic-to-metal, both of which are presumably superior to metal-to-polyethylene articulations. As discussed elsewhere herein, hydrogels, shape-memory polymers, or other polymers within the cylinder provide a cushion, or dampen the forces across the plates. Polymers of different durometers could be used in cylinders in different locations. For example, the polymers in the posterior cylinders could be less compressible and therefore help resist extension of the spine. The cylinders could also use liquids with baffles to dampen motion. That said, hydrogels or polymers have the benefit of functioning without a water tight cylinder piston unit. Indeed, as mentioned previously, the cylinders or the pistons may contain holes to allow fluid movement in the hydrogel configurations.

As discussed above, this invention is not limited to the spine, but may be used in other joint situations such as the knee and hip, which typically use polyethylene bearing surfaces on the acetabulum or proximal tibia. Problems related to polyethylene wear are well known to orthopedic surgeons. Although metal-on-metal and ceramic-on-ceramic total hips have been developed to reduce the problems associated with poly wear, such designs do not provide shock-absorbing capacity. For example, excessive force from tight ligaments about the knee or hip may reduce the size of the hydrogel, thus reducing the tension on the ligaments. Conversely, loose ligaments will cause the hydrogel to swell, thus increasing the tension on the loose ligaments. Although hydrogels are used in this preferred embodiment as well, other elastomers and polymers including shape memory polymers may alternatively be used.

Figure 16 is a cross-sectional view of a tibial component according to the invention. The compressible/resilient material is depicted at 98. Channels 99 may be provided for fluid transfer, and these may be located around the periphery, or near the center, rather than in the weight-bearing area. Figure 17 is a drawing which shows how a locking component 100 may be incorporated in the design which allows movement while, at the same time, prevent disassociation. A similar design may be used for other prosthetic components, including a patella button.

Figure 18 is a side-view cross-section of a tibial component for a knee replacement utilizing a central guide 102 and peripheral pistons 104, 106, much like the vertebral embodiments discussed with reference to Figures 7-11, in particular.

Figure 19 is a side-view drawing of an embodiment illustrating the way in which the invention may be applied to the hip. As shown in the drawing, an inner cup 108 would be used with respect to the acetabulum, along with an outer bearing surface with a compressible/resilient material such as a hydrogel/elastomeric or other polymeric material 110 being used therebetween. Particularly with regard to a hydrogel configuration, one or more channels 112 for fluid transfer may be provided.

Figure 20 is a sagittal cross section of the spine and a single cylinder embodiment of the ADR drawn in Figure 7. Keels 114, 116 from the ADR EPs project into the vertebrae above and below the ADR.

Figure 21A is a sagittal cross section of an alternative embodiment of the ADR. The cushion element 120 is located into a somewhat flexible shell 122. The shell 122 in this case completely isolates the cushion element from exposure to the fluids of the body. The walls of the shell reversibly bend in response to axial loads. The shell could be made of plastic, polyethylene, or a flexible metal such as titanium. The upper ADR EP articulates with the shell. The shell may either articulate with lower ADR EP or the shell may snap into the lower ADR EP. The shell could be filled with a liquid form of the cushion material. The cushion material could polymerize, or cure, within the shell. The thickness of the walls of the shell could vary. For example, the top and bottom of the shell could be thicker than the sides of the shell. The thin side walls would encourage bending through the side walls rather than the top and bottom of the shell. Figure 21B is a sagittal cross section through another embodiment of the ADR drawn in Figure 21A. The cushion material is

- 14 -

contained within a hollow area in the inferior ADR EP. The upper and lower ADR EPs articulate.

Figure 22 is a sagittal cross section of an alternative embodiment of the ADR drawn in Figure 5A. The bottom component of the ADR drawn in Figure 5A has a keel to attach the ADR to the vertebra inferior to the ADR. The upper component of the ADR drawn in Figure 5A articulates with an ADR EP. The gap between the walls of the ADR and the cushion element allow the cushion element to expand radially with axial compression. Elastomers that contain air, such as "foam polyurethane" require less space for expansion with axial loads. The air within the elastomer is compressible.

Figure 23A is a sagittal cross section through another embodiment of an ADR according to the invention, wherein the cushion element 124 is contained between ADR EPs. A flexible band 126 attaches to the upper and lower ADR EPs to prevent exposure of the cushion element to the fluids of the body. The cushion element may not be attached to either ADR EP. Fluid, such as an oil, gel or other suitable fluid, could be contained within the ADR. Alternatively, the outer, flexible band could be fluid permeable to permit fluid transfer in hydrogel containing embodiments.

Figure 23B is a sagittal cross section of the embodiment of the ADR drawn in Figure 23A, showing how a portion of the outer band 126 can be detached from one of the ADR EPs to create a window into the ADR, allowing the cushion element 124 to be replaced through the window. The cushion element could be sealed by a "fluid tight" membrane. The fluid tight membrane could also contain a fluid. The outer band could be reattached to the upper ADR EP after changing the cushion element. Hydrogel containing embodiments would not require a detachable outer band. The hydrogel containing embodiment could be placed into the disc space with a partially dehydrated hydrogel. The outer band would no longer be required to provide a fluid impermeable barrier. Further, in Figure 23A, the outer, flexible band could be fluid permeable to permit fluid transfer in hydrogel containing embodiments. Note also that in Figure 23B, the hydrogel containing embodiments would not require a detachable outer band since the device could be placed into the disc space with a partially dehydrated hydrogel.

Figure 23C is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 23B, wherein the cushion element is capped with a material

- 15 -

that reduces friction between the ADR EPs and the cushion component. For example, polyethylene or chrome cobalt caps could press fit into the top and bottom of the cushion element.

Figure 24A is a sagittal cross section through another embodiment of the invention, including a novel keel that limits shear stress on the cushion element. Such a keel preferably allows at least 10 degrees of flexion, 5 degrees of extension, and 2.5 degrees of lateral bending in each direction, and 2 degrees of axial rotation in each direction. A donut shaped cushion element 130 surrounds the keel. Figure 24B is a coronal cross section through the ADR drawn in Figure 24A. The keel 132 of the upper ADR EP cooperates with a slot 134 within the lower ADR EP to allow the motions mentioned above.

Figure 25 is a lateral view of the spine and a multi-component embodiment of the invention, wherein multiple cushion components are connected together. For example, the components can be connected to a band that surrounds the components. The cushion components could rotate about axles connected to the band. Figure 26 is a sagittal cross section of an embodiment of the invention, wherein upper and lower components 136, 138 are connected by a flexible tension band 140. The band prevents dissociation of the components.

Figure 27 is a view of the top of an alternative embodiment of the ADR drawn in Figure 11A, wherein the cylinders 140, 142 that cooperate with the pistons are elongated to allow translation. Alternatively, the cylinders could have a central torodial region to allow translation.

Figure 28A is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 13, including at least one piston connected to the upper ADR EP by an axle or axles such as 146. Figure 28B is a coronal cross section of the embodiment of the ADR drawn in Figure 21A. Such hinged pistons facilitate ADR flexion and extension. A loose fit between the piston and the cylinder would also permit a few degrees of lateral bending. A single piston embodiment allows unlimited axial rotation. The piston or pistons can be located centrally or in non-central locations. For example, the piston could be located in the posterior half of the ADR.

Figure 29A is a coronal cross section of a constrained embodiment of the invention, wherein the balls on the pistons will not fit through the openings in the

- 16 -

cylinders of the ADR. Figure 29B is an exploded anterior view of the ADR drawn in Figure 22A. The balls 148, 149 for the pistons are threaded onto the pistons through openings 150, 152 on the bottom of the inferior ADR EP. Screws 154, 156 can be used to close the openings in the inferior ADR EP.

5 Figure 30 is a sagittal cross section of an alternative embodiment of the invention, wherein the shaft 158 of the piston is located eccentrically on the ball at the end of the piston. The shaft of the piston selectively impinges with the walls of the cylinder to limit ADR motion. For example, the impingement could limit ADR extension.

10 Figure 31 is a sagittal cross section of an alternative embodiment of the invention, wherein the shaft of the piston selectively impinges on a projection from the walls of the cylinder to limit ADR motion. For example, the impingement could limit ADR extension.

15 Figure 32 is a lateral view of an alternative embodiment of the invention, wherein a slot allows the axle to translate forward and backward, facilitating translation of the ADR EPs.

20 Figure 33A is a sagittal cross section of an alternative embodiment of the invention, wherein a ball-and-socket joint 159 is located in the posterior aspect of the ADR. A cushion element 160 is located anterior to the ball and socket joint 159. The cushion element could be made of polymers or springs. Figure 33B is a view of the top of the elastomeric component and the socket of the inferior ADR EP drawn in Figure 33A.

25 Figure 34 is a sagittal cross section of an alternative embodiment of the invention, including a projection from the piston or pistons fit through a slot in the top of the cylinder/cylinders. The two ADR EPs can be rotated after inserting the projection through the slot thus, reversibly locking the ADR EPs together. The projection could also interact with the top of the cylinder to limit ADR motion.

30 Figure 35A is a sagittal cross section of the spine and an alternative embodiment of the invention, including a piston and cylinder containing members articulate with the vertebral endplates, they are not fastened to the endplates of the vertebrae. All of the embodiments drawn in this application could be converted into similar "disc spacer" ADRs. Articulation between the components can be located centrally or eccentrically. For example, the articulation may be located in the

- 17 -

posterior half of either component or both components. The drawing illustrates a posterior location of the articulation.

Figure 35B is a sagittal cross section through another "disc spacer" embodiment of the invention, wherein the end of the piston contains a spherical enlargement. For example, the ball and socket of Figure 9A shown in my co-pending
5 U.S. Patent Application entitled "Artificial Intervertebral Disc Spacers," incorporated here by reference in its entirety, can be surrounded by a viscoelastic or other compressible/resilient component. Figure 35C is a sagittal cross section through another embodiment of the invention, wherein the disc spacer articulates with ADR
10 EPs as described the co-pending application discussed above. Figure 35D is a sagittal cross section through another embodiment of the invention, wherein the piston component projects from the inferior ADR EP. The cylinder component articulates with the piston component and a superior ADR EP. This two-articulation embodiment is similar to a "cushioned" embodiment of the two articulation ADRs is
15 also described in the co-pending U.S. patent application referenced above.

Figure 36A is a lateral view of a variation including a superior ADR EP that articulates with convex caps which, in turn, articulate with, or are connected to, springs. The articulation between the ADR EP and the caps reduces shear on the springs and on the connection of the springs to the surrounding components. Figure
20 36B is a view of the top of the convex caps and the bottom ADR EP of the embodiment of the ADR drawn in Figure 36A. Any number of springs and caps can be used in the novel ADR. For example, the ADR could use one to twenty springs or more.

Figure 36C is a sagittal cross section through an embodiment of the ADR
25 similar to that drawn in Figure 36A. The inferior ADR EP in Figure 36C has posts that hold the springs in position. Figure 36D is a sagittal cross section through the ADR drawn in Figure 36C. The upper ADR EP is tilted with respect to the lower ADR EP as would be seen with spinal movement. The spring on the left is compressed. The post from the inferior ADR EP is articulating with the spring cap.
30 Articulation between the spring cap and the post, limit the amount of compression applied to the spring. Movement occurs through the articulation between the spring cap and the upper ADR EP, and between the spring cap and the post from the lower ADR EP.

- 18 -

Figure 37A is a lateral view of an alternative embodiment of an ADR according to the invention, wherein the springs articulate directly with the ADR EPs. The superior ADR EP has convex surfaces that articulate with the springs. The lower ADR EP could have similar convex surfaces. Alternatively, the springs could be
5 connected to or articulate with a flat surface on the lower ADR EP.

Figure 37B is a sagittal cross section of an embodiment of the ADR similar to that drawn in Figure 37A. The springs surround posts from the inferior ADR EP. The surface on the top of the post is concave to articulate with the convex projections from the upper ADR EP. The ADR also has an optional component to seal the
10 springs and the articulating surfaces from the body. The seal traps debris from the articulating surfaces. The seal can also be used to contain a lubricating fluid. Various oils or other suitable fluids or gels could be used inside the ADR.

Figure 38 is a lateral view of an alternative embodiment of an ADR, wherein multiple springs cooperate with a single cap. Figure 39 is a sagittal cross section
15 through an alternative embodiment wherein the caps and springs are contained in cylinders. Figure 40 is a lateral view of an alternative embodiment wherein the top of the spring caps are concave rather than convex as drawn in Figure 20A.

Springs of other types can be used in this and the other embodiments of this invention. For example, Figure 41A is a lateral view of an alternative embodiment
20 illustrating the use of a C-shaped spring that cooperates between convex projections from the ADR EPs. Figure 41B is a sagittal cross section through the embodiment of the ADR drawn in Figure 41A. Figure 41C is a view of the top of the springs and inferior ADR EP drawn in Figure 41A. Figure 41D is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 41A. The C-shaped springs
25 are preferably circular in cross section. Figure 41E is a sagittal cross section through the embodiment of the ADR drawn in Figure 41D. The inferior ADR EP has posts to hold the springs in position. The springs articulate with the flat surface of the inferior ADR EP.

Figure 42 is a lateral view of the spine and an alternative embodiment
30 including spring caps that articulate with a vertebral endplate. The use of independent springs allow the ADR to better conform to the vertebral endplate. For example, one or more of the springs can extend more completely to fill concavities within the vertebral endplates.

Figure 43A is a lateral view of an embodiment of the invention applied to total knee replacement. A cushion element 202 is located between two metal components 204, 206. The tibial component preferably further includes a polyethylene piece 210. Figure 43B is sagittal cross section of the embodiment of the device drawn in Figure 43A. At least one piston configuration is used to limit shear force on the cushion element. Figure 43C is a view of the bottom of upper metal component. A single piston 220 can be seen on the bottom of the component.

Figure 43D is a view of the bottom of an alternative embodiment of the component drawn in Figure 20C incorporating two pistons 240, 250. Two or more pistons can be used to eliminate rotation between the two metal, or ceramic, components. Eliminating rotation also reduces the shear stresses on the cushion component. Figure 43E is a coronal cross section of the embodiment of the device drawn in Figure 43D.

Figure 44A is a sagittal cross section of an alternative embodiment including an arrangement to lock the components together. A projection 260 from the side of the piston fits into a slot shaped opening 262 in the top of the cylinder. Rotating the two components traps the projection from the piston in the cylinder. Figure 44B is a view of the top of the cylinder component of the device drawn in Figure 44A, illustrating the oblong cylinder opening.

Figure 45A is a sagittal cross section of an alternative embodiment including a different locking mechanism. The assembled components are locked together. Figure 45B is an exploded view of the embodiment of the invention drawn in Figure 45A. The cushion element is illustrated at 270. A preferably circular component 272 is threaded onto the piston, after the piston is placed through cushion component and into the cylinder. A screw 274 is used to close the bottom of the cylinder.

Figure 46 is a sagittal cross section through another embodiment of the invention, wherein a tibia component pistons in the lower component. A seal 280 can be seen between the two components (dark circles). The upper component also has one or more pistons that move within cylinders in the lower component. The upper and lower components can be non-circular in shape to prevent rotation.

Figure 47 is a sagittal cross section through another embodiment of the device. The cushion element (area of the drawing with diagonal lines) is contained within

- 20 -

cylinders in the tibial and femoral canals. A membrane is used to seal the tibial component. Seals are also illustrated on the femoral components (dark circles).

Figure 48 is a sagittal cross section of an alternative embodiment of the invention including hydrogel as a cushion element 302. A flexible, preferably fluid permeable membrane 304 surrounds the hydrogel. Axial loads on the hydrogel are converted into hoop stress on the flexible membrane. In the preferred embodiment the flexible membrane is elastic. The flexible membrane or components above and below the hydrogel may contain pores for fluid transfer. This embodiment of the device is also described in co-pending U.S. patent application Serial No. 10/407,554, entitled "Artificial Intervertebral Disc Replacements Incorporating Reinforced Wall Sections."

Figure 49 is a sagittal cross section of an alternative embodiment of the invention wherein the cushion element is enclosed within a flexible metal component. The cushion component, a sealed elastomer, or hydrogel, for example, is not exposed to the fluids of the body, which can degrade some materials. A somewhat similar device is described in co-pending provisional patent application Serial No. 60/445,489, entitled "Improved Longevity Elastic Components For ADRs."

Figure 50 is a sagittal cross section of another embodiment of the invention, wherein an elastic component surrounds pieces that move along inclined planes. Loads on the upper tibial component force the moveable outward. The cushion component forces the movable components together as the load is removed from the tibial component. The elastic component is not exposed to shear or compression. The elastic component is only exposed to tension. This embodiment of the device is also described in co-pending provisional patent application Serial No. 60/445,958, entitled "Composite Components For Disc And Joint Replacements."

I claim:

- 21 -

1. A cushioned prosthesis configured for use with a bone having an
2 articular surface, comprising:
a compressible component; and
4 a force-transfer component disposed between the compressible member and
the articular surface of the bone.
2. The cushioned prosthesis according to claim 1, wherein the
2 compressible component is a hydrogel.
3. The cushioned prosthesis according to claim 2, further including one or
2 more channels through the housing or piston to permit fluid transfer.
4. The cushioned prosthesis according to claim 1, wherein the
2 compressible member is a synthetic rubber, hydrogel, elastomer, viscoelastic polymer,
shape-memory polymer, or foam polyurethane.
5. The cushioned prosthesis according to claim 1, wherein the force-
2 transfer component has a surface physically configured to interact with a vertebral
endplate.
6. The cushioned prosthesis according to claim 1, wherein the force-
2 transfer component has a surface physically configured to interact with one or more
natural or artificial femoral condyles.
7. The cushioned prosthesis according to claim 1, wherein the force-
2 transfer component has a surface physically configured to interact with a natural or
artificial proximal tibia.
8. The cushioned prosthesis according to claim 1, wherein the force-
2 transfer component has a surface physically configured to interact with a natural or
artificial femoral head.
9. The cushioned prosthesis according to claim 1, wherein:

- 22 -

2 the compressible component is sealed within a housing; and
the force-transfer component form on of the walls of the housing.

10. The cushioned prosthesis according to claim 1, further including a
2 device to limit the movement of the force-transfer component.

11. The cushioned prosthesis according to claim 10, wherein the device
2 includes a piston and cylinder arrangement.

12. The cushioned prosthesis according to claim 11, wherein the piston
2 terminates in a ball-shaped end.

13. The cushioned prosthesis according to claim 11, wherein the piston
2 and cylinder arrangement has an asymmetric cross section.

14. The cushioned prosthesis according to claim 1, wherein the force-
2 transfer component is contained within a housing with sidewalls to limit shear stress.

15. The cushioned prosthesis according to claim 1, wherein compressible
2 component in combination with the force-transfer component form an intervertebral
disc spacer.

16. The cushioned prosthesis according to claim 15, further including a
2 pair of opposing endplates between which the disc spacer is positioned.

17. The cushioned prosthesis according to claim 1, wherein the
2 compressible component is a spring or springs.

18. The cushioned prosthesis according to claim 17, further including a
2 pair of opposing plates; and
the spring or springs are disposed between plates to urge them apart.

- 23 -

19. The cushioned prosthesis according to claim 18, further including a
2 concave or convex surface on one of the plates where one of the springs contacts that plate.

20. The cushioned prosthesis according to claim 19, further including one
2 or more features that impinge or otherwise limit the load on the spring or springs.

21. The cushioned prosthesis according to claim 20, including a spring
2 disposed in a cylinder.

22. The cushioned prosthesis according to claim 20, including a spring
2 disposed over a post.

23. The cushioned prosthesis according to claim 19, wherein the point
2 where the spring contacts the concave or convex surface results in a joint having a center of rotation.

24. The cushioned prosthesis according to claim 23, wherein the joint is
2 spherical.

25. The cushioned prosthesis according to claim 23, including a plurality
2 of springs, each forming a joint having a center of rotation.

26. The cushioned prosthesis according to claim 25, wherein the centers of
2 rotation cooperate to form an overall center of rotation for the ADR.

27. The cushioned prosthesis according to claim 1, further including a
2 mechanism that allows the force-transfer component to telescope while limiting a full pull-out.

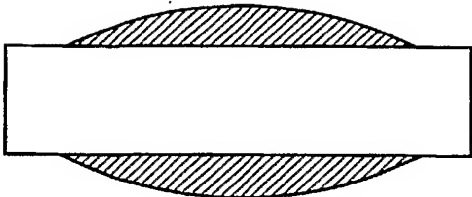


Fig - 1A

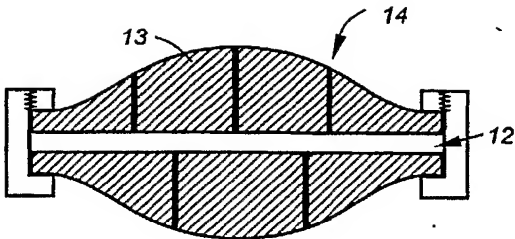


Fig - 1B

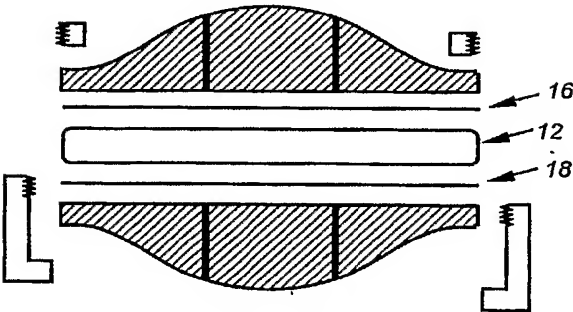


Fig - 1C

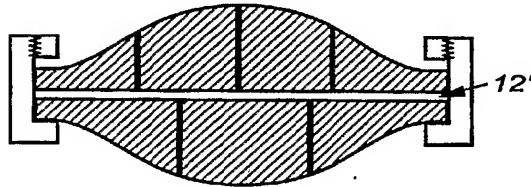


Fig - 1E

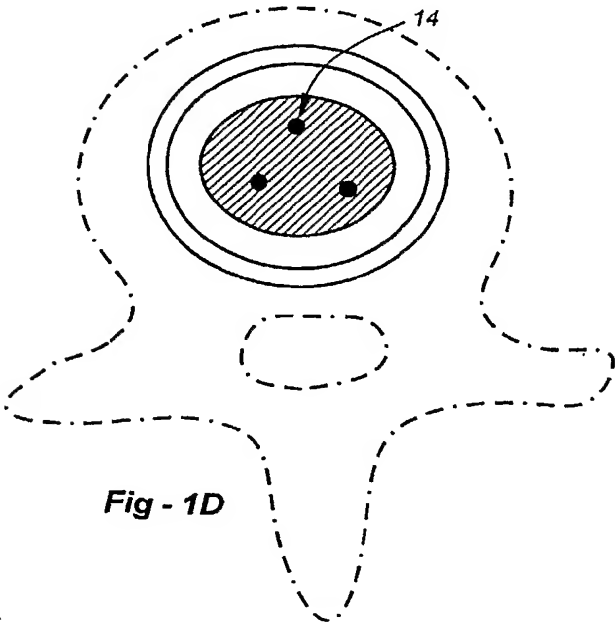


Fig - 1D

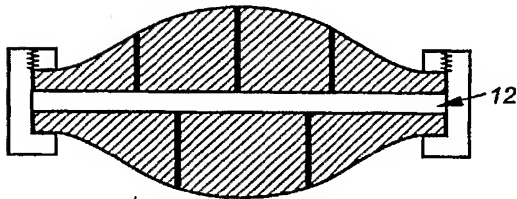


Fig - 1F

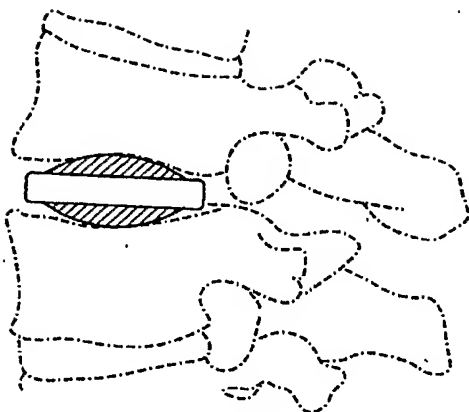


Fig - 2A

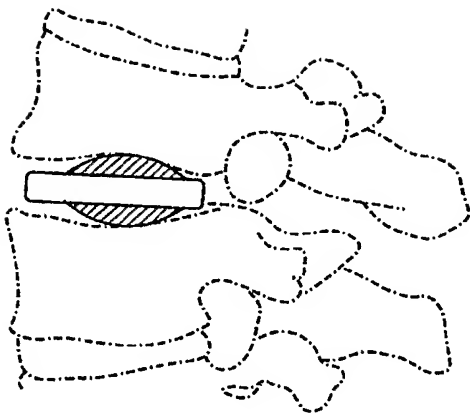


Fig - 2B

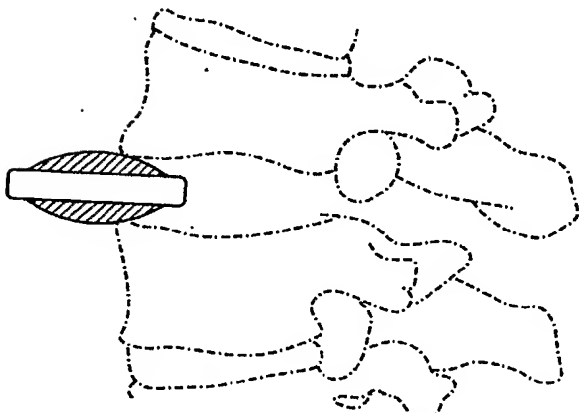


Fig - 3A

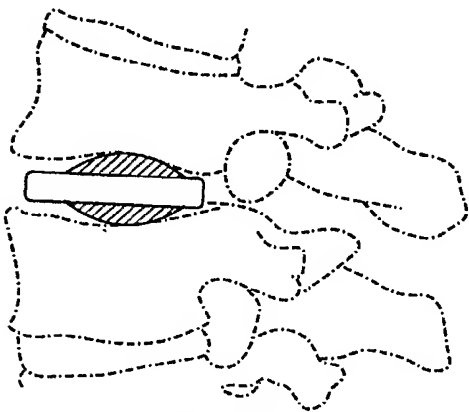


Fig - 3B

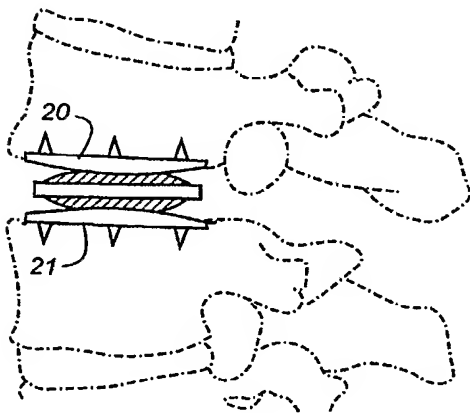


Fig - 4A

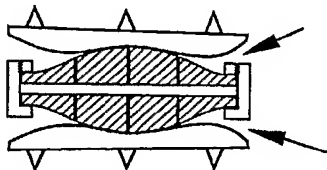


Fig - 4B

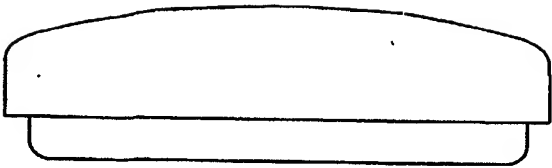


Fig - 5A

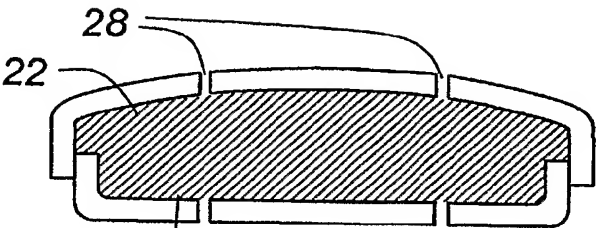


Fig - 5B

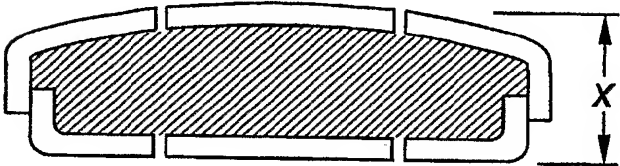


Fig - 5C

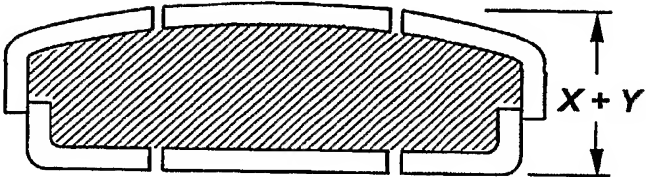


Fig - 5D

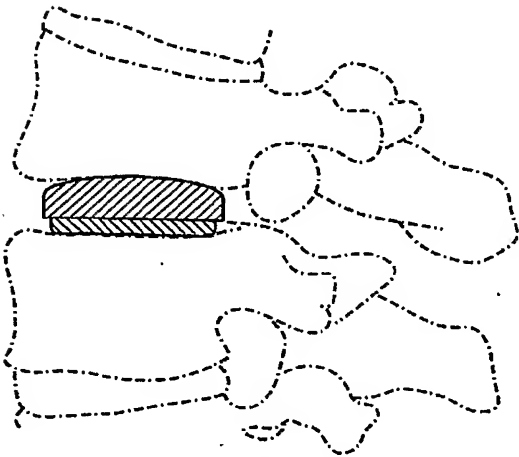


Fig - 5E

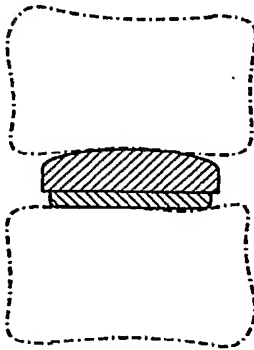


Fig - 5F

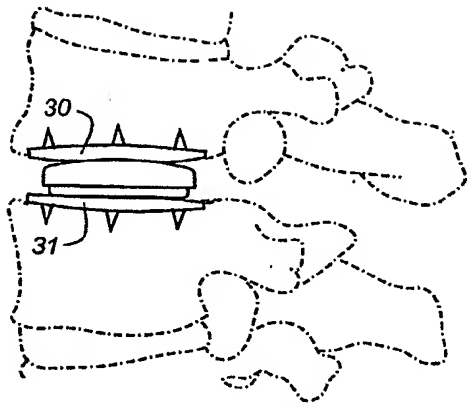


Fig - 6A

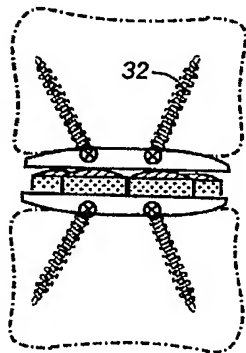
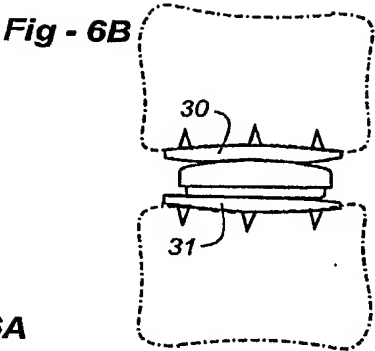


Fig - 7A

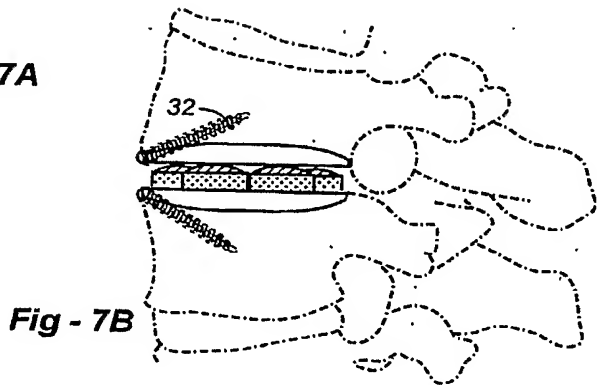


Fig - 7B

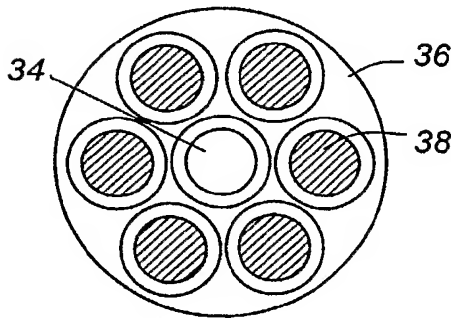
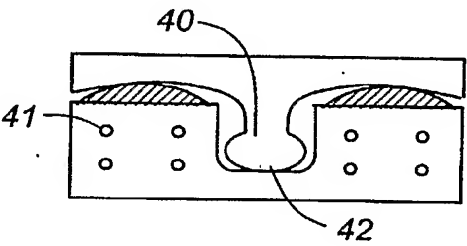


Fig - 7C



-OR-

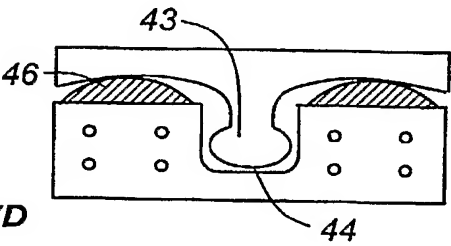


Fig - 7D

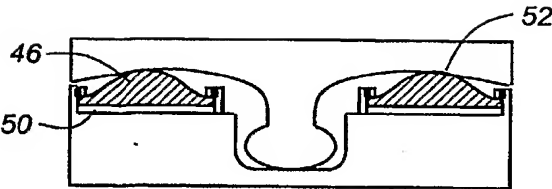


Fig - 8A

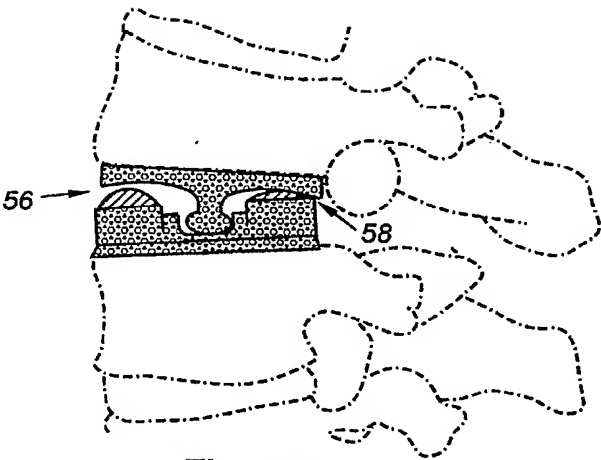


Fig - 8B

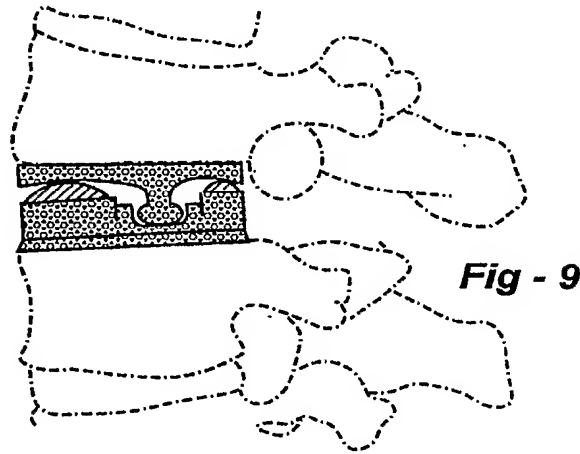


Fig - 9



Fig - 10B



Fig - 10C

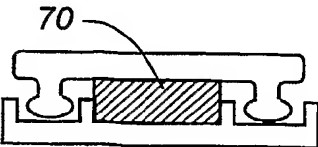


Fig - 11B



Fig - 11C

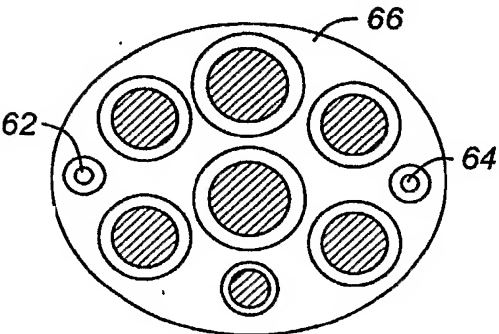


Fig - 10A

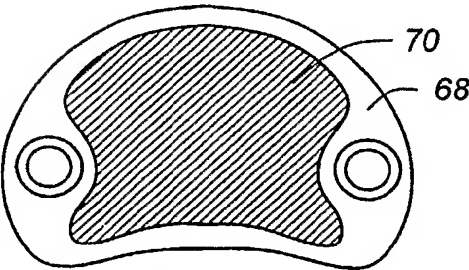


Fig - 11A

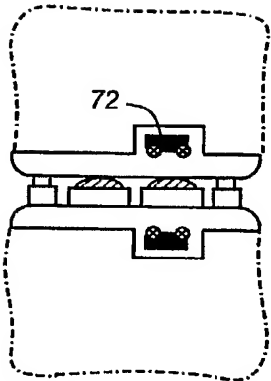


Fig - 12A

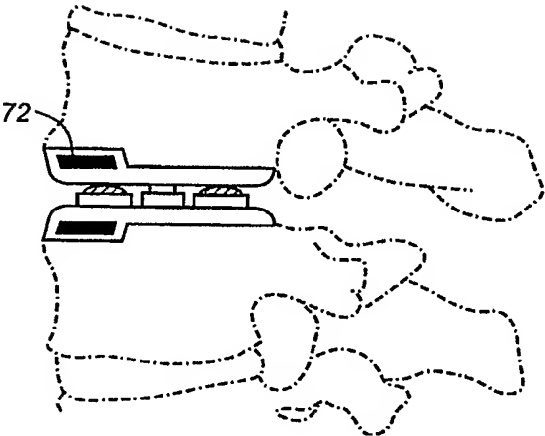


Fig - 12B

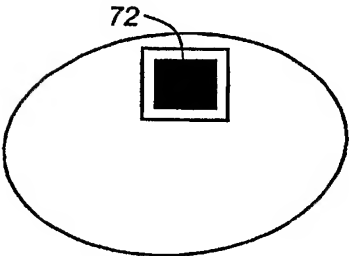


Fig - 12C

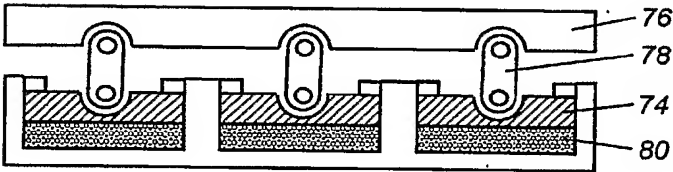


Fig - 13

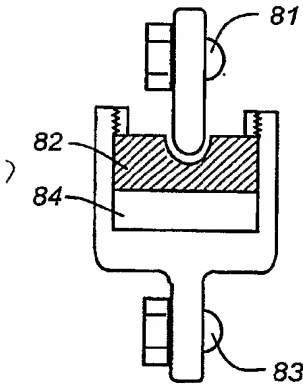


Fig - 14A

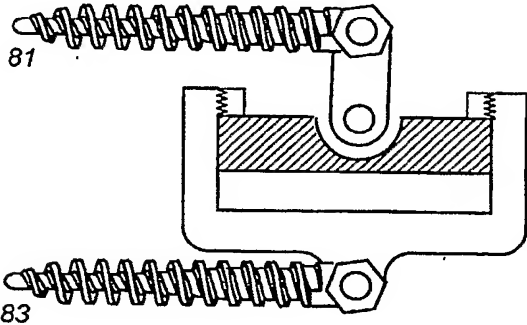


Fig - 14B

7/15

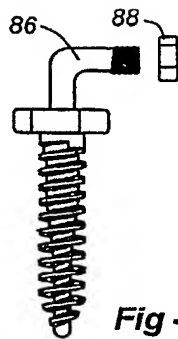


Fig - 15A

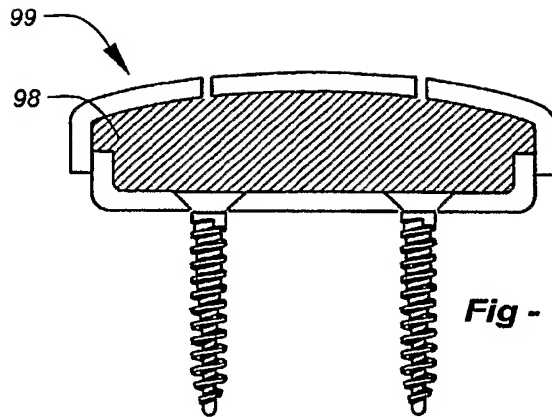


Fig - 16

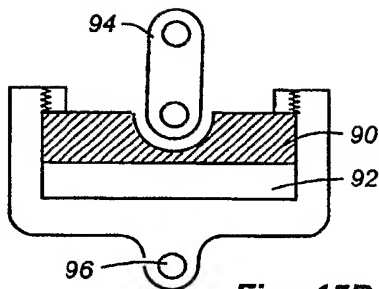


Fig - 15B

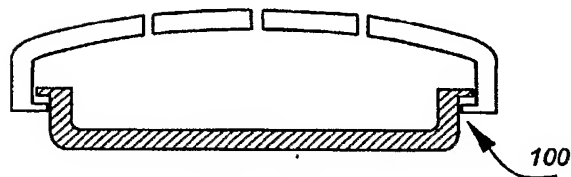


Fig - 17

Fig - 18

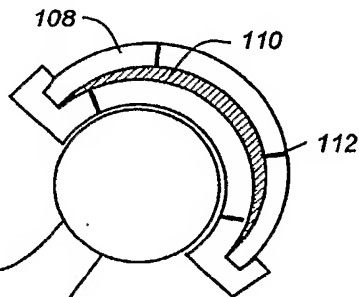
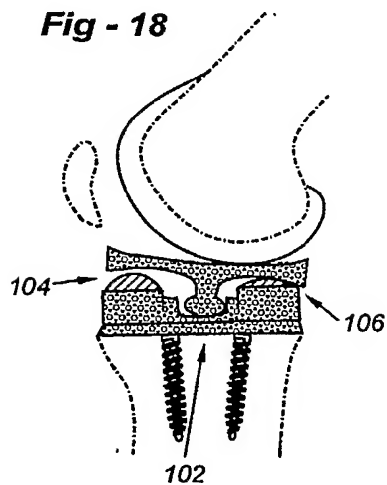


Fig - 19

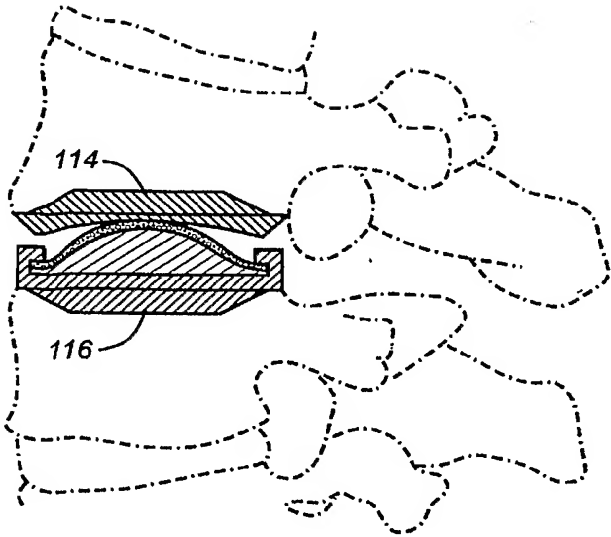


Fig - 20

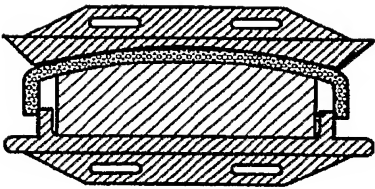


Fig - 22

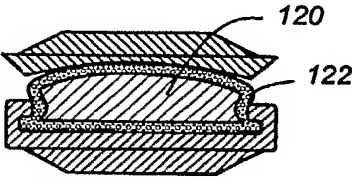


Fig - 21A

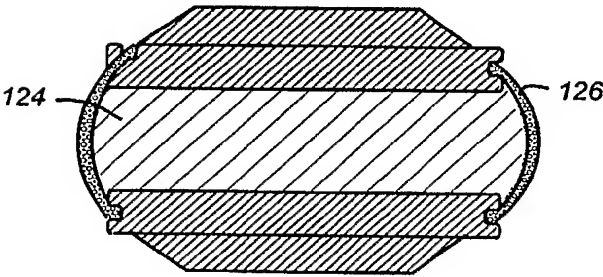


Fig - 23A

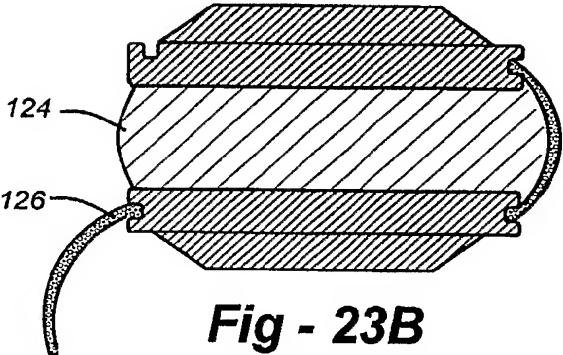


Fig - 23B

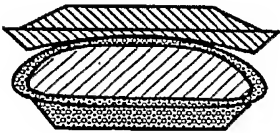


Fig - 21B

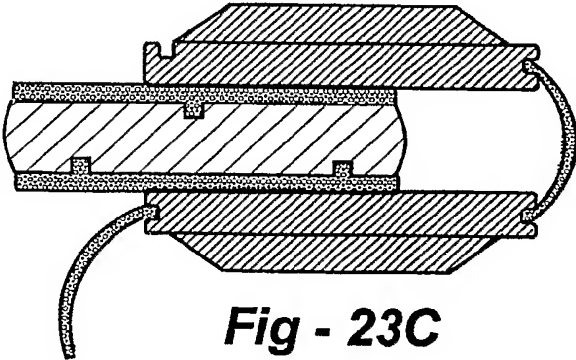


Fig - 23C

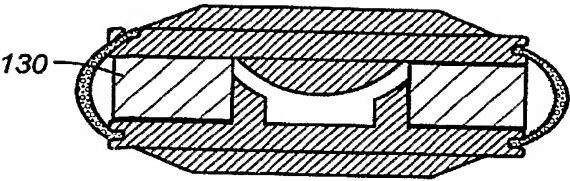


Fig - 24A

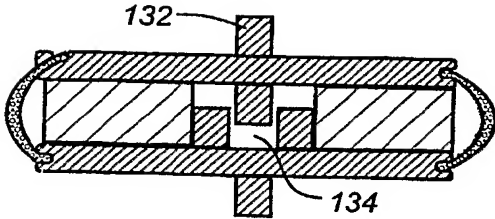


Fig - 24B

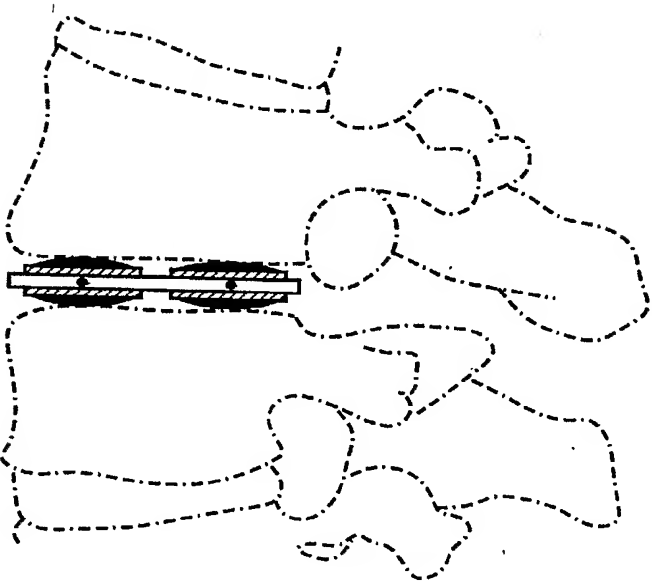


Fig - 25

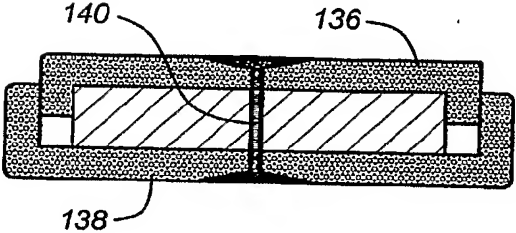


Fig - 26

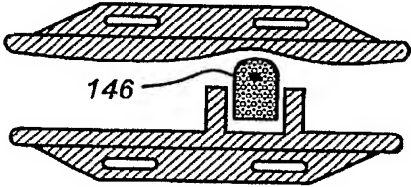


Fig - 28A

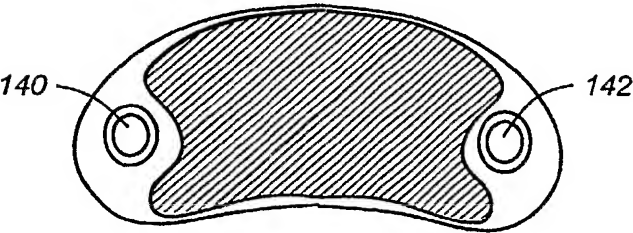


Fig - 27

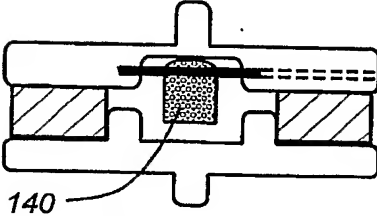


Fig - 28B

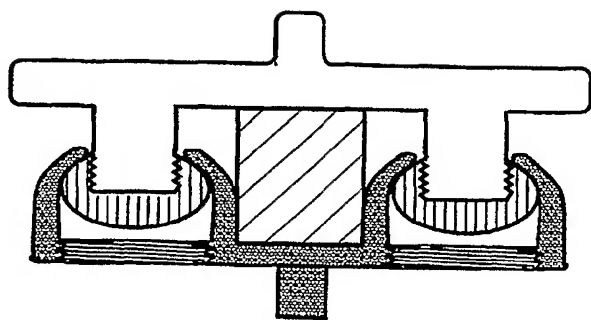


Fig - 29A

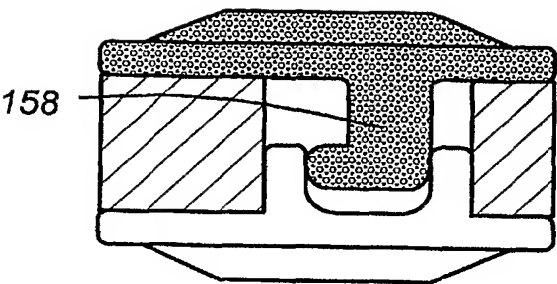


Fig - 30

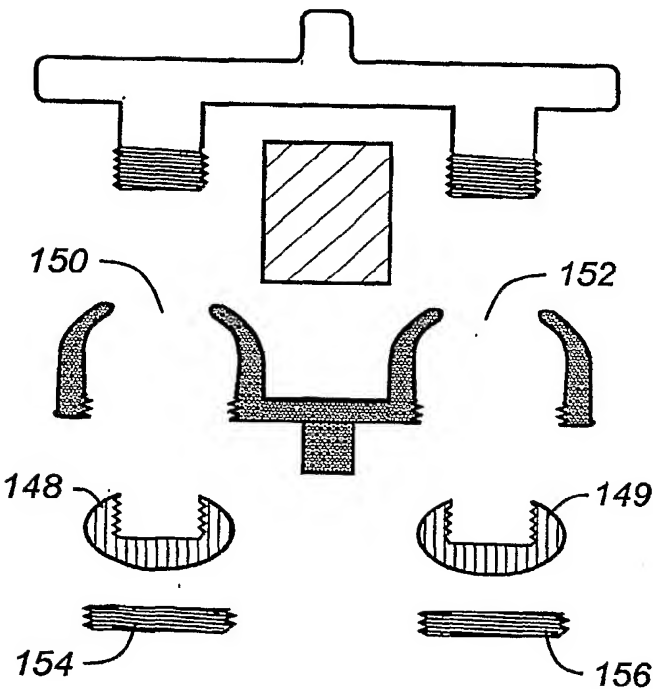


Fig - 29B

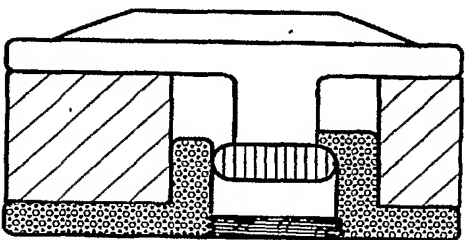


Fig - 31

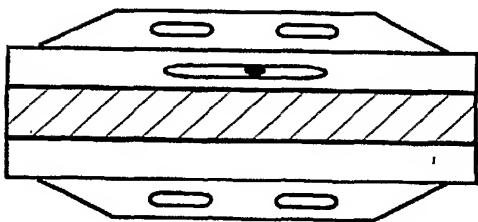


Fig - 32

11/15

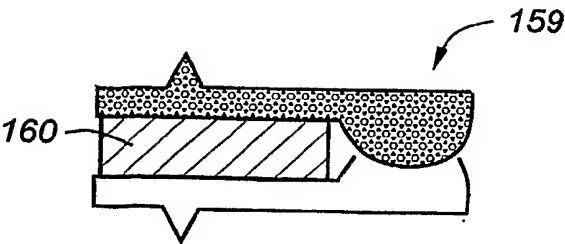


Fig - 33A

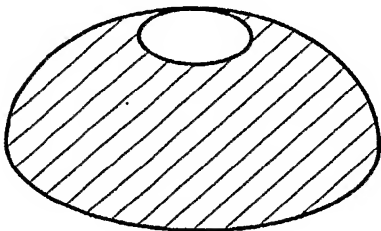


Fig - 33B

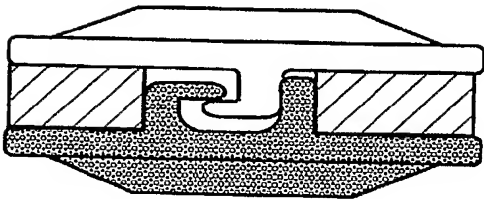


Fig - 34

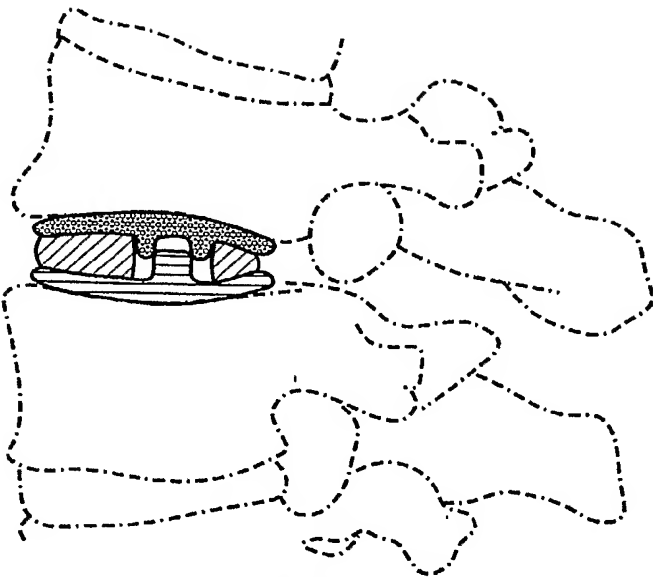


Fig - 35A

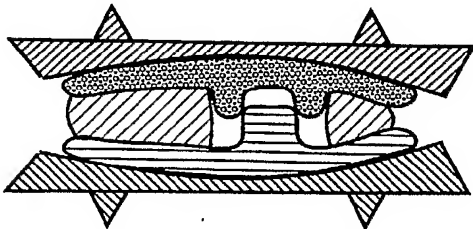


Fig - 35C

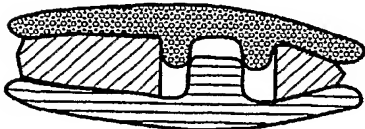


Fig - 35B

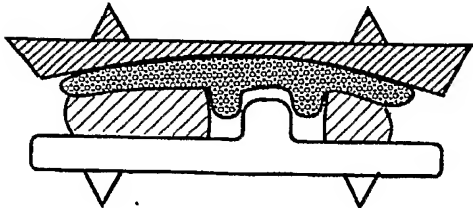


Fig - 35D

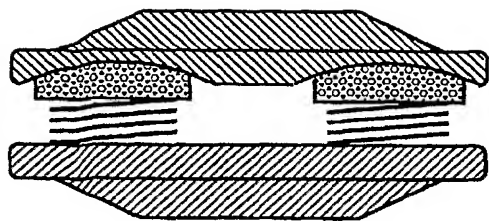


Fig - 36A

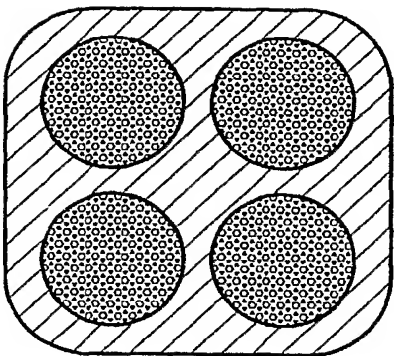


Fig - 36B

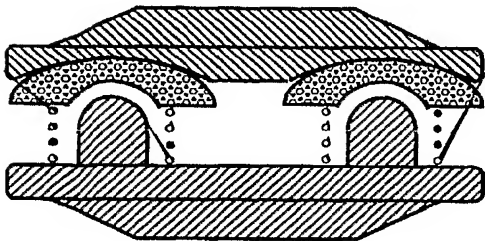


Fig - 36C

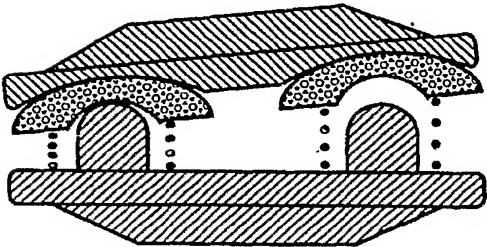


Fig - 36D

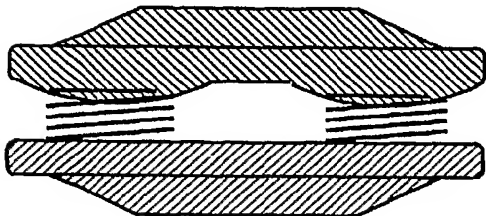


Fig - 37A

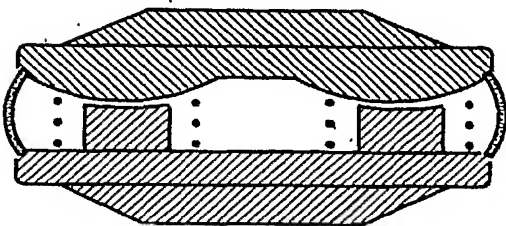


Fig - 37B

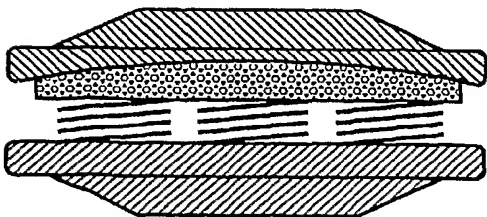


Fig - 38

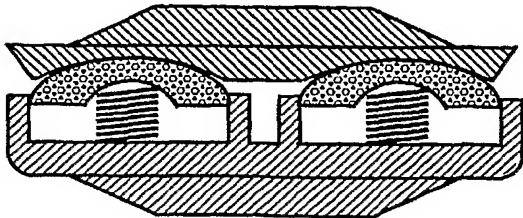


Fig - 40

13/15

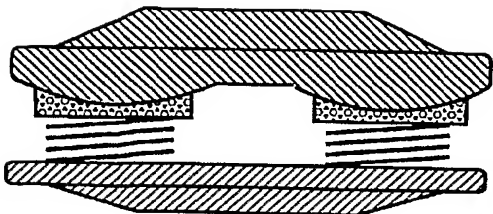


Fig - 40

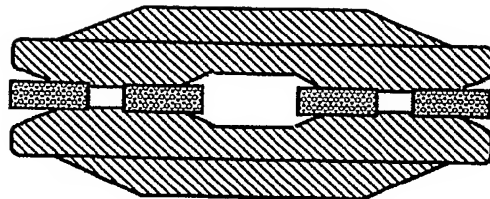


Fig - 41A

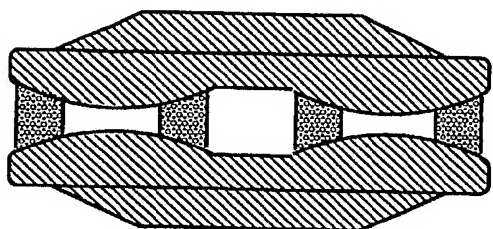


Fig - 41B

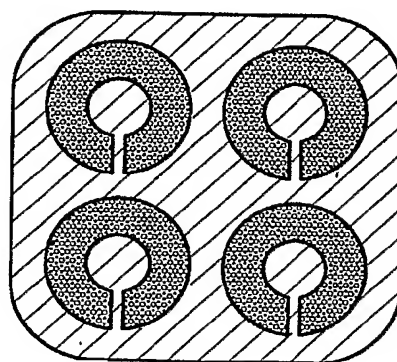


Fig - 41C

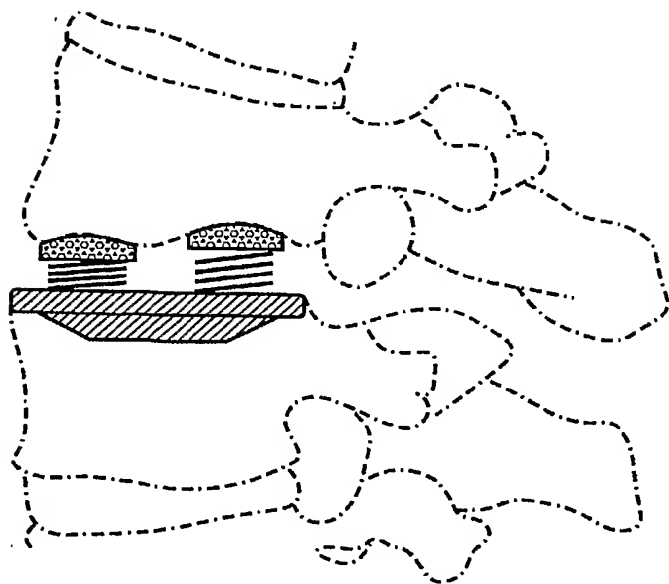


Fig - 42

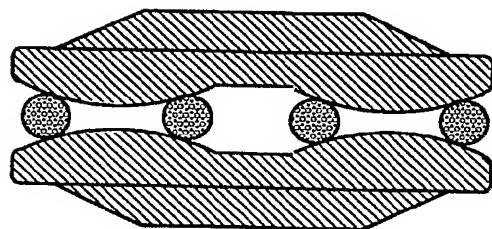


Fig - 41D

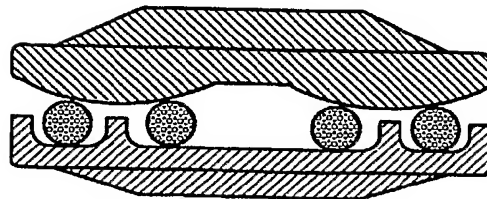


Fig - 41E

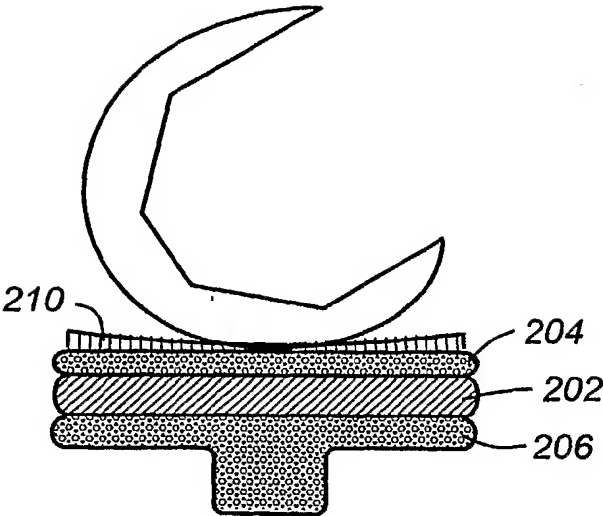


Fig - 43A

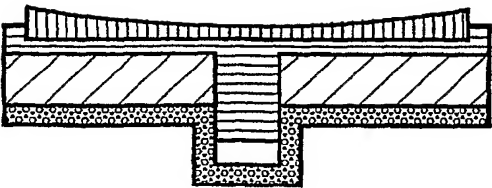


Fig - 43B

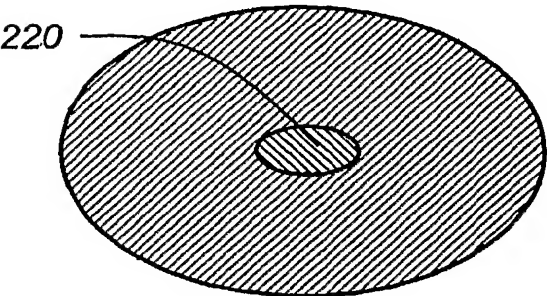


Fig - 43C

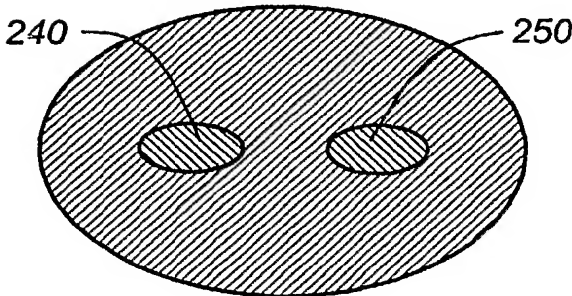


Fig - 43D

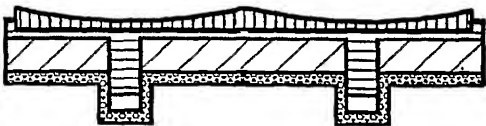


Fig - 43E

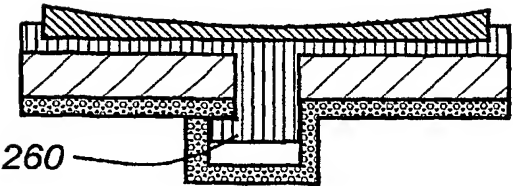


Fig - 44A

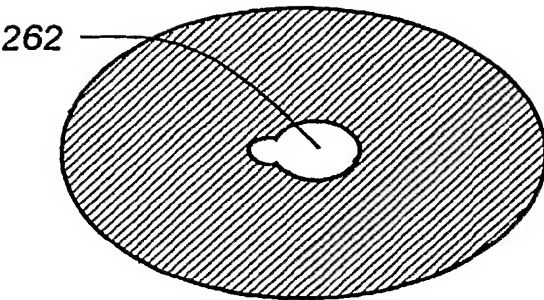


Fig - 44B

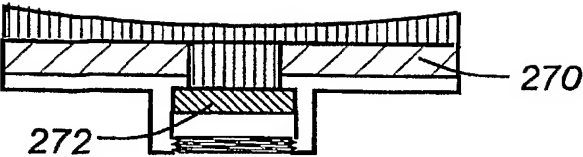


Fig - 45A

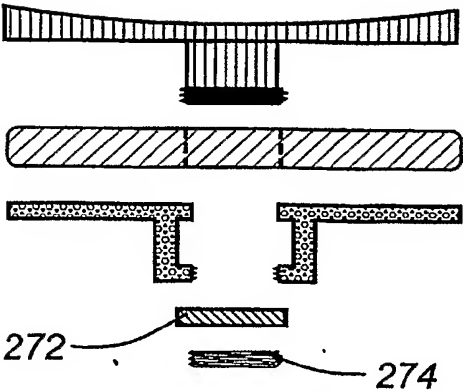


Fig - 45B

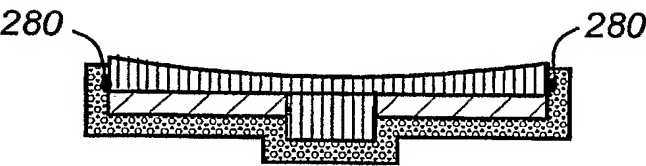


Fig - 46

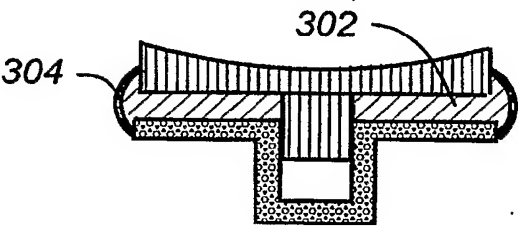


Fig - 48

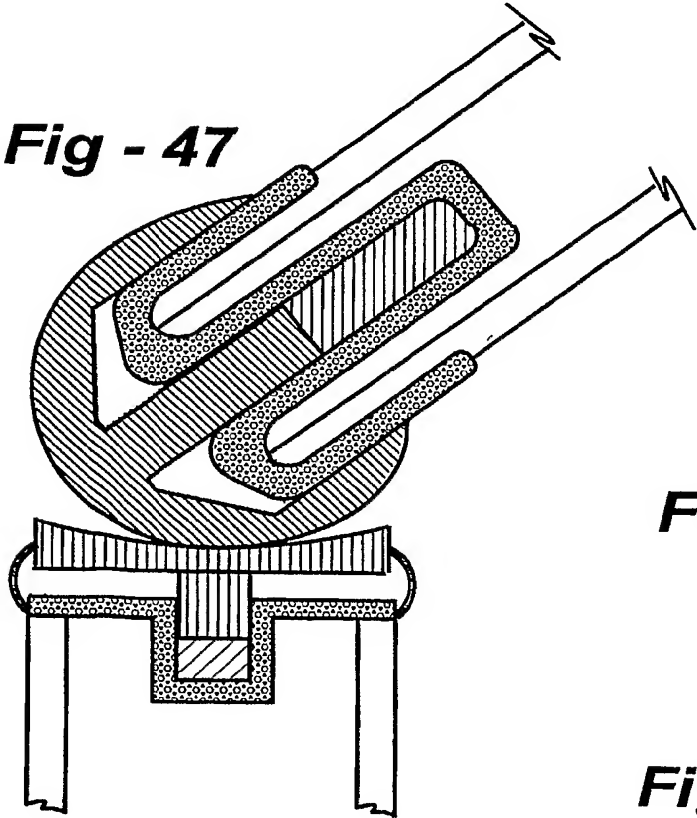


Fig - 47

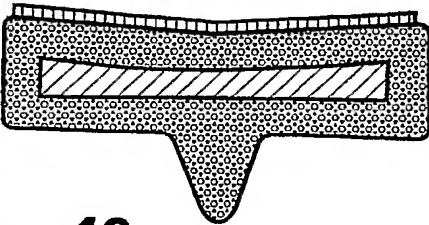


Fig - 49

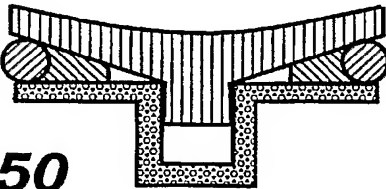


Fig - 50

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/14764

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/44
US CL : 623/17.15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/17.15, 17.11, 17.12, 17.13, 20.11, 20.28, 22.13, 22.14, 23.17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/64385 A (LI et al) 02 November 2000, see entire document including page 15, lines 16-20 teaching external surfaces, walls, barriers, supports, etc.	1-10, 14-16
X	US 4,309,777 A (PATIL) 12 January 1982, see entire document.	1, 5, 9-11, 14-18
X, P	US-6,508,841 B2 (MARTIN et al) 21 January 2003, see all embodiments and column 4, lines 3-15, teaching "compression or elongation".	1, 6-11, 14, 17, 27
X	US 5,389,107 A (NASSAR et al) 14 February 1995, see all embodiments.	1, 8-11, 14, 17, 27
X, P	US 6,527,806 B2 (RALPH et al) 04 March 2003, see entire document.	1, 5, 10, 14-21, 23, 25-27



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:		"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier application or patent published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

08 July 2003 (08.07.2003)

Date of mailing of the international search report

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P.O. Box 1450
Alexandria, Virginia 22313-1450

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International Bureau



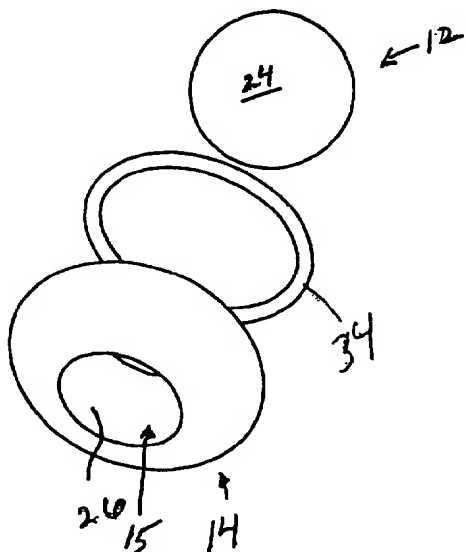
(43) International Publication Date
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10/282,620 29 October 2002 (29.10.2002) US
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(54) Title: ARTIFICIAL INTERVERTEBRAL DISC DEVICE



(57) Abstract: Artificial disc devices (10) are disclosed that restore correct anatomical intervertebral spacing for damaged discs while maintaining a substantially normal range of biomechanical movement for the vertebrae between which they are implanted. The disc devices (10) include center bearing (12) and outer or annular bearing portions (14) with the center bearing portion (12) including generally axially extending locating surfaces (16 & 18) which cooperate with the facing vertebral surfaces to resist migration. The outer bearing portion (14) is for load bearing or load sharing with the center bearing portion (12) and includes surfaces (28 & 32) that extend radially toward the periphery of the vertebrae so that subsidence about the center bearing portion (12) is minimized. Alternate forms of the disc devices include one with an axially enlarged center ball bearing (92) having an annular ring bearing extending (82) thereabout and another having upper and lower plate members (20 & 22) with a central bumper member (36) and a surrounding resilient annular member (14) therebetween.

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ARTIFICIAL INTERVERTEBRAL DISC DEVICE

Background of the Invention

Artificial disc technology has been employed to correct damaged
5 spinal discs for relieving back pain and restoring or maintaining
intervertebral spacing while attempting to minimize their constraining
effects on the normal biomechanical movement of the spine. Two types of
artificial discs have generally been employed: the artificial total disc which
is designed to substitute for the entire disc, i.e. the annulus, nucleus and
10 possibly the end plates as well; and the artificial nucleus where only the
nucleus is replaced with the annulus and end plates remaining intact. The
disc of the present invention is not intended to be limited to one or the other
of the above types.

A number of prior artificial disc devices include upper and lower
15 members that are rigidly fixed to the adjacent upper and lower vertebrae.
These fixed members sandwich a bearing therebetween along which they
can slide to allow for relative movement between the adjacent vertebrae,
see, e.g. U.S. Patent Application Publication 2002/0035400. However,
devices such as these usually require special surface materials and/or
20 surface treatments that allow for bone ingrowth for fixing the members to
the vertebrae. Moreover, these devices have had problems with migration
where the intermediate bearing body shifts out from between the vertebrae,

and thus generally require more complex shapes to form stops for resisting such disc shifting.

In a relatively early approach, a stainless steel ball was employed in the damaged disc area. The ball approach, while effective to provide a good range of motion, tended to create subsidence problems. Over time, the ball would crush into the end plates as loading was fairly concentrated over a small surface on the ball in engagement with the plates. In other words, since these ball implants were not of a size that enabled the load of the spine to be distributed evenly thereacross, the end plates tended to subside or fall around the ball.

There also has been focus on simply replacing the nucleus with a gelled substance either injected directly in the disc or provided in pouches to attempt to reinflate the annulus and provide for load bearing. However, these approaches are limited in their use to patients who have a substantially undamaged disc annulus.

Accordingly, there is a need for an artificial disc that does not significantly inhibit spine movement while still providing the load bearing and spacer functions akin to that of a normal, healthy spinal disc.

Summary of the Invention

In accordance with one form of the present invention, an artificial disc device is provided including a central, enlarged bearing portion and an outer, annular bearing portion generally extending about the central

bearing portion and allowing for movement therebetween. The inner or central, enlarged bearing portion preferably has a body including upper and lower arcuate surfaces or surface portions that can shift relative to the outer bearing portion as well as with respect to the confronting surfaces of the spine, such as the end plates of the vertebrae. In this regard, the arcuate surfaces are not rigidly fixed to the vertebrae and are curved so as to allow the upper and lower vertebrae to shift with respect to each other such as when the spine is bent from side to side or front to back and twists or turns. At the same time, the enlarged central bearing portion can engage in small indentations in the respective vertebral surfaces that keeps the central bearing in a relative locked position thereby preventing lateral shifting with respect to the vertebrae so that the implant does not migrate despite the shifting vertebrae above and below these bearing surfaces. Thus, the enlarged central bearing portion locates the artificial disc device relative to the vertebrae.

The main body of the central bearing or bearing portion or bearing assembly including the arcuate bearing surfaces thereof can be a hard metallic material or alloy for load bearing purposes. Alternatively, a hard plastic could be employed to provide the central bearing portion with resiliency under compressive loading. For shock absorption, the bearing body may be provided with a hollow core or one that is liquid or gel filled or filled with other elastic material. For example, the bearing body could be formed of a resilient membrane that is inflated with an incompressible fluid,

e.g. saline, and then sealed. To vary the give or compressibility of the central bearing body, the size of the core could be enlarged or decreased accordingly, or the modulus of elasticity of the body material can be varied.

In one preferred form, the outer bearing portion has a body that includes radially inner surfaces adjacent the arcuate surfaces adapted or configured for allowing relative movement therebetween. The outer bearing shares the compressive loading generated between the vertebrae via upper and lower bearing surfaces or surface portions thereof so that the load is better distributed across the present artificial disc device minimizing localized forces thereon. With the provision of the outer bearing, the present device is well suited to avoid subsidence problems as could occur in prior devices having highly localized loading thereon.

The outer bearing or bearing assembly also may be constructed to provide improved shock absorption capabilities such as with an inner portion of the body that is softer than the harder outer portion. For example, an elastomeric layer of material can be employed between attached upper and lower bearing plates of the outer bearing, or the core layer of an annular portion and/or an inner ball bearing portion of the outer bearing can be of elastomeric or liquid gelled material. Similar to the central bearing, the outer bearing could be formed of a resilient membrane that is inflated within incompressible fluid, e.g saline, and then sealed. Manifestly, material combinations can also be employed to achieve desired shock absorption proportions. The outer bearing can further include a

compression limiter so as to maintain proper tolerances between the outer bearing inner surfaces and the inner bearing surfaces in confronting relation therewith as the outer bearing is loaded. In this manner, the inner bearing maintains its freedom of movement despite the compressive loading that is being borne by the outer bearing, as will be described more fully hereinafter.

In one form, the artificial disc includes a central ball as the enlarged, central bearing portion with an annular body of the outer bearing extending thereabout. The upper and lower load bearing surfaces or surface portions of the outer bearing body preferably do not project axially as far toward the upper and lower vertebrae as the ball surface portions such as by having a larger radius of curvature than the radius of the ball. In other words, the load bearing surface portions have a more gradual curvature than the center bearing surface portions or for that matter they can have a flat configuration. This allows the enlarged ball to seat in the indents in the end plates for positioning the artificial disc securely between the vertebrae while the annular body is also effective in taking up the compressive loading between the upper and lower vertebrae.

In another form, the central bearing portion includes a pair of generally dome-shaped shell members that ride on a generally spherical inner bearing portion integral with the outer bearing portion for sliding thereover. In this regard, the inner bearing portion is integrally connected to the outer bearing portion via a circumferential web wall. The domes or

shells are sized relative to the inner spherical bearing portion so that there are gap spaces between the peripheral edges of the domes and the web wall. The web wall positions the outer, annular load bearing portion such that interference with shifting of the domes on the central spherical bearing portion is minimized. Alternatively, snap-fitting the domes in place over the inner ball bearing portion could be employed; however, the above described loose-fitting construction is preferred to minimize binding of the dome shells under compressive load forces. In this manner, the domes can readily slide on the inner ball portion and, at the same time, the vertebral end plates or other vertebral surfaces in engagement with the arcuate surfaces of the domes can also shift with respect thereto to provide a bi-polar device with two interfaces that shift with respect to each other.

By having this bi-polar artificial disc construction, the stress and wear that would otherwise occur in either of the interfaces is decreased as one bearing interface can be shifting when the load on the other becomes too great. Lubricant can be provided between the dome shells and the inner bearing portion to reduce friction and wear therebetween. A seal ring attached adjacent or at the end edge of the shells for being carried therewith minimizes lubrication leakage while allowing the shells to slide over the spherical surface of the inner bearing portion in a low friction manner.

Brief Description of the Drawings

FIGS. 1A-1E are directed to various views of one form of an artificial disc implant device in accordance with the present invention showing an enlarged spherical central bearing and an outer annular bearing;

FIGS. 1F-1J are directed to various views of a disc device slightly modified over that shown in FIGS. 1A-1E to better conform to the vertebrae;

FIGS. 2A-2D are directed to various views of the artificial disc device of FIGS. 1A-1E as implanted between adjacent upper and lower vertebrae;

FIGS. 3A-3D are directed to various views of an alternative artificial disc in accordance with the present invention showing a pair of dome shells that ride on an inner, spherical bearing portion integral with the outer annular bearing portion;

FIGS. 4A-4D are directed to various views of the artificial disc device of FIGS. 3A-3D implanted between upper and lower vertebrae;

FIGS. 5A-5E are directed to various views of an artificial disc device similar to that shown in FIGS. 3A-3D except having a circumferential groove extending about the periphery of the outer bearing portion;

FIGS. 6A-6F are directed to various views of another artificial disc device in accordance with the present invention showing a pair of outer, annular bearings that fit about an enlarged, central spherical bearing;

FIGS. 7A-7C are directed to various views of an alternative construction of the central bearing showing opposing dome shells, one having a central post projection and the other having a central hub;

FIGS. 8A-8E are directed to various views of an artificial disc device including the dome shells of FIGS. 7A-7C projecting into an opening formed in the inner bearing portion;

FIG. 9 is a cross-sectional view of an alternate form of the artificial disc device of FIGS. 8A-8E showing a pair of inner bearing rings on which the respective dome shells ride with a cushion web wall therebetween.

FIGS. 10A-10D are directed to various views of another alternative artificial disc device having an axially enlarged central bearing member and an outer, annular bearing member showing an hour-glass configuration for the central-bearing member and an apertured body of the outer bearing member;

FIGS. 10E-10H are directed to a modified version of the disc device of FIGS. 10A-10D showing different sizes of through apertures formed in the outer bearing member;

FIGS. 11A-11H are directed to various views of alternative artificial disc devices showing upper and lower bearing members and a load bearing member therebetween; and

FIGS. 12A-12I are directed to various views of an alternative disc device showing upper and lower plate members, and an annular load bearing member and a plug member therebetween.

Detailed Description of the Preferred Embodiments

Referencing FIGS. 1A-1E, an artificial disc device 10 is shown which includes an enlarged, central bearing portion 12, and a substantially

annular, outer bearing portion 14 having a through opening 15 in which the central bearing portion 12 is disposed. Herein, preferred shapes, configurations and material selections for the inner and outer bearing portions are set forth. However, in each case, these selections are not meant to be limiting as other selections that serve the purpose of the disc implant described herein are also contemplated. Likewise, several embodiments are disclosed that have structural features that can be implemented substantially interchangeably among the disc implants.

In the form illustrated in Figs. 1A-1E, the central bearing 12 has an axially enlarged body 13 relative to the outer bearing 14 so that it generally includes arcuate surface portions 16 and 18 that project above and below the radially outer bearing portion 14 for engaging in indents in confronting surfaces 20a and 22a of the adjacent upper and lower vertebrae 20 and 22, respectively, for seating the implant 10 therein. In the implant device 10, the central bearing 12 can be in the form of a generally spherical ball such that the surface portions 16 and 18 are part of the outer spherical surface 24 thereof. The annular bearing portion 14 has a generally ring-shaped (e.g. circular, oval or ellipsoidal) body 17 that includes an arcuate inner side surface 26 extending about the opening 15 that faces the ball bearing 12 having generally the same radius of curvature as that of the spherical ball surface 24 so that the ball bearing 12 can substantially freely rotate in the small, concave indents, divots or depressions 27 and 29 formed in the vertebrae confronting surfaces in which the ball 12 seats, as described above

and shown in Figs. 2A-2D. At the same time, the vertebral surfaces 20a and 22a, and particularly the concave indents 27 and 29 formed therein can readily slide over the ball surface 24. The configuration and rotation of the ball bearing 12 allows the spine vertebrae 20 and 22 to substantially
5 undergo the normal range of biomechanical movement such as when the patient is twisting their back and/or bending it in various directions.

When the implanted disc 10 undergoes compressive loading, the outer bearing 14, and in particular the upper and lower surface portions 28 and 30 thereof will substantially maintain the effective spacing between the
10 vertebrae 20 and 22. Thus, in the present artificial disc device 10, the outer ring bearing body 17 shares the loading with the ball bearing body 13 created between the dynamically moving vertebrae 20 and 22 so as to avoid subsidence problems as occurred with prior ball bearing-type devices. Accordingly, in the disc 10, the outer bearing 14 generally will not allow the
15 end plates to subside around the ball bearing 12.

As shown, the curvature of the upper and lower surface portions 28 and 30 of the outer bearing body 17 is more gradual than that of the arc surface portions 16 and 18 of the central ball bearing body 13 to provide it with a doughnut-type configuration. Accordingly, in the device 10, the
20 surface portions 28 and 30 are part of a substantially continuously curved outer ring bearing surface 32 such that they curve around the radially outermost point 29 of the outer bearing body 17 to form an outwardly projecting convex configuration 29 for the outer surface 32 of the annular

bearing 14. As such, the surface portions 16 and 18 extend to their greatest spacing at the central section 17a adjacent the central opening 15 of the bearing body 17. At the thickest section 17a, the spacing of the surface portions 16 and 18 is less than the diameter of the ball bearing 12 so that the surface portions 16 and 18 protrude from the opening 15 to extend above and below the respective outer bearing surface portions 28 and 30 for engaging in the concave depressions 27 and 29. The gradual curvature of the surface portions 28 and 30 allows the ring bearing 14 to better conform to the general concavity of the vertebral surfaces 20a and 22a including any attached end plates over time. By way of example and not limitation, the ball bearing diameter can be approximately between 6-18mm and the maximum thickness of the outer bearing section 17a can be approximately 16mm. Manifestly, these sizes are to be tailored according to the anatomy of the patient being treated.

Referring to FIGS. 1F-1J, artificial disc device 10a is depicted which has a slightly modified wedged or bulged configuration for corresponding outer bearing body 14' thereof. More particularly, as can be seen in the cross-sectional view of FIG 1J, the outer bearing body 14' has a thickened section 17a and thinner section 17b as measured between the corresponding upper and lower surface portions 28a and 30a with these sections being generally diametrically opposite each other with a smooth transition therebetween. Since the confronting vertical surfaces 20a and 22a will normally be in a non-parallel orientation relative to each other, the section

17a of the disc device 10a will better conform to the area between the surfaces 20a and 22a that are spaced further from each other with the section 17b fitting better in the more confined, closely spaced area between the vertebrae surfaces 20a and 22a allowing the implant device 10a to be tightly
5 fit or wedged between the vertebrae 20 and 22.

With the vertebrae 20 and 22 exerting compressive loading on the artificial disc device 10, the projecting surface portions 16 and 18 of the center ball bearing 12 will securely engage in the indented recesses 27 and 29 in the confronting vertebral surfaces 20a and 22a for seating the ball
10 bearing 12 therein. As the spine moves causing relative shifting of the vertebrae 20 and 22 about the ball bearing 12 with it freely rotating in the recesses 27 and 29 as necessary, further loading is exerted on the device 10, with the surface portions 28 and 30 of the outer annular bearing 14 being effective to share with the ball bearing 12 the compressive loading that is
15 generated between the vertebrae 20 and 22, and which further can act as a shock absorber for the high impact load bearing that may be needed between the vertebrae 20 and 22, such as described hereinafter. In this manner, the present artificial disc device 10 resists both migration by the seating of the central ball bearing 12 as well as avoiding subsidence
20 problems by providing load bearing which is well distributed across a large radially extending surface area of the device 10 as by the device upper surfaces 16 and 28 and lower surfaces 18 and 30. For example, the distance

from the central axis 19 of the ring bearing 14 extending through the opening 15 to the outer end 29 can be approximately 12mm.

While other material selections are possible, it is presently contemplated that the inner ball bearing 12 preferably will be of a harder material than the outer bearing 14 so that the harder ball 12 is more apt to maintain its conformity with and thus stay seated in the indents 27 and 29 in the surfaces 20a and 22a. In this regard, the ball 12 can be of a biocompatible material including titanium or metallic material such as stainless steel, while the ring bearing 14 can be of a material of a lower modulus of elasticity such as plastic material, e.g. polyethylene, so as to have some resilience under compressive loading forces.

With a plastic outer bearing 14, a support hoop 34 of a harder material than that of the outer bearing 14 such as of metal material similar to that of the ball bearing 12 can be embedded therein. Generally, the hardness of the ball bearing 12 and the hoop 34 will both be greater than the outer bearing 14, although they may not be the same as each other. For example, the hoop 34 can be of a hard metal material whereas the center bearing 12 can have a hardness similar to the human bone. To this end, the plastic outer bearing 14 can be a molded component of the artificial disc device 10. As such, the metal support hoop 34 can be molded in situ in the outer ring bearing 14. The support hoop 34 serves as a compression limiter to resist deformation of the resilient plastic ring bearing 14 due to the compressive loading generated between the vertebrae 20 and 22 so that it is

better able to maintain its configuration despite the stresses exerted thereon. In addition, the hoop 34 also resists shear forces generated by spinal movements for reducing such forces in the resilient material of the outer bearing 14.

5 Alternatively, outer bearing body 17 can have an inner core portion that is of different and softer material than that of the harder outer portion so that the annular bearing 14 has improved shock absorbing properties for high force impacts on the artificial disc 10 with the harder outer layer minimizing wear on the bearing 14. For example, the wear layer can be of
10 hard polyethylene material with the inner cushion material of the bearing body 17 being of a softer polymeric or elastomeric material. In another alternative, the body 17 can include a hollowed inner portion or includes an outer resilient membrane that is filled with liquid, e.g. saline, or gel or other elastic material, e.g. Hydrogel and/or polyurethane, for shock absorption
15 purposes.

 Figures 3A-3D and 5A-5E are directed to alternative artificial disc devices 36 and 38, respectively. The disc devices 36 and 38 are of similar construction as each include a central bearing portion 39 formed from two opposing shells 40 and 42 having a generally dome-shaped configuration
20 riding on a central or inner, spherical ball bearing portion 44 that can be formed integrally with a body 43 of radially enlarged bearing 46 including outer bearing portion 45 thereof. Opposite upper and lower annular arcuate spaces 43a and 43b are formed in the body 43 separating the bearing

portions 44 and 45 by a distance greater than the thickness of the shells 40 and 42 so that respective shell end portions 47 and 49 fit therein allowing the dome shells 40 and 42 to slide on the ball bearing portion 44.

Other differences in the construction of the bearing 46 of the devices

5 36 and 38 relates to the plan configuration of the outer bearing portion 45.

The devices 36 and 38 have their bearing portion 45 provided with a pair of lobe sections 48 and 50 that extend in a continuously curved path about the majority of their peripheries until the lobe perimeters meet at their juncture formed at a recessed area 52 therebetween. In this manner, the plan shape
10 of the lobed bearing 46 more closely approximates that of the vertebrae 20 and 22 between which the devices 36 and 38 are implanted. Ring bearing 14 could be provided with a similar lobed plan configuration. Manifestly, the outer bearings 14 and 46 can be formed with other configuration, e.g. oval in plan, so as to be more closely match that of the intervertebral space in which
15 they are to be implanted.

Another difference resides in the configurations of load bearing surface portions 54 and 56 of the bearing 46 generally corresponding to the load bearing surface portions 28 and 30 of the bearing 14. In contrast to the curvature of the surfaces 28 and 30 of the ring bearing 14, the surfaces 54
20 and 56 are shown as having a generally flat, parallel configuration so that the bearing body 43 has more of a disc or plate-like configuration.

Generally, however, some curvature on these bearings surfaces 54 and 56 will be desirable although perhaps modified from that shown for bearing

surfaces 28 and 30 for the implant 10. The surfaces 54 and 56 are provided with a spacing smaller than that of the diameter of the central bearing portion 44 and thus of the central bearing assembly 39 with the dome shells 40 and 42 thereon so that they project above and below the respective

5 surfaces 54 and 56. In this manner, the dome shells 40 and 42 are able to seat in indents 27 and 29 in the vertebral surfaces 20a and 22a like the bearing ball surface portion 16 and 18. To this end, the shells 40 and 42 can be of harder material than that of the bearing body 43, and particularly the ball bearing portion 44 thereof. Accordingly, similar to the ball bearing 12,
10 the dome shells 40 and 42 can be of a ceramic material or a stainless-steel metal, titanium or alloys thereof, whereas the ring bearing 46 is preferably of a plastic or polymer material such as polyethylene to provide it with stiffness and resiliency under compressive loading. The bearing 46 could also be of like material to that of the dome shells 40 and 42 for higher load
15 bearing capacity.

The dome shells 40 and 42 are sized relative to the spherical bearing portion 44 such that there are gap spacings 57 between peripheral end edges 58 and 60 of the respective shells 40 and 42 at their largest diameters and web wall 62 in the bearing 46, as best seen in the cross sectional views of
20 Figs. 3D and 5D. Accordingly, the diameter across the end edges 58 and 60 of the dome shells is less than the diameter of the ball bearing portion 44. In use, the dome shells 40 and 42 can slide to take up these spaces 57.

The web wall 62 extends laterally or radially and centrally from the ball bearing portion 44 to the annular load bearing portion 45 that extends about the ball bearing portion 44 on which the shells 40 and 42 ride. The circumferential web wall 62 extends radially for a sufficient distance, such
5 that the outer bearing portion 45 is spaced from the ball bearing portion 44 to provide recesses 43a and 43b large enough to allow the dome edges 58 and 60 to slide into engagement with the web wall 62 without encountering interference from the annular load bearing portion 45 of the bearing 46.

In the device 38, the annular bearing portion 45 includes a radially
10 inner surface 51 that extends generally axially or tangentially to outer spherical surface 44a of the inner bearing portion 44, albeit spaced slightly therefrom via web wall 62. In this manner, the corresponding spaces 43a and 43b in the body 43 of the device 38 are enlarged over those in device 36 such that overhanging portions of the bearing portion 45 that can be
15 compressed against the dome shell portions 47 and 49 and potentially cause binding in the spaces 43a and 43b are avoided.

With the above-described construction, the artificial disc devices 36 and 38 have a bi-polar construction in that relative movement between the vertebrae 20 and 22 and the dome shells 40 and 42 can occur along with
20 relative movement between the dome shells 40 and 42 and the ball bearing portion 44. Generally, the smooth surface interface between inner surfaces 40a and 42a of the respective shells 40 and 42 and the outer surface 44a of the ball bearing portion 44 will have a lower coefficient of friction

therebetween than that between outer surfaces 40b and 42b of the respective shells 40 and 42 and the indents 27 and 29 in the vertebrae surfaces 20a and 22a. Thus, there will be some differential shifting that can occur with the moving components of the devices 36 and 38 such that generally the domes 40 and 42 will more readily shift along the ball bearing portion 44 prior to shifting of the dome shells 40 and 42 with respect to the vertebrae 20 and 22. Such differential articulation keeps wear between the higher coefficient of friction surfaces to a minimum as sliding can preferentially occur between the smooth inner arcuate surfaces 40a and 42a of the respective shells 40 and 42 and the outer surface 44a of the ball bearing portion 44. Alternatively, if the coefficient of friction is lower between the vertebrae surface concave indents 27 and 29 and the shell outer surfaces 40b and 42b, then of course shifting will preferentially occur at this interface of the disc devices 36 and 38 keeping wear at the higher friction interface between the shell inner surfaces 40a and 42a and ball surface 44a to a minimum. Of course, as the spine is undergoing various dynamic forces during the movements it is required to undertake, oftentimes both interfaces of the bi-polar devices 36 and 38 will be shifting simultaneously to provide the spine with the necessary biomechanics while also keeping undue wear on the disc devices 36 and 38 to a minimum.

Figs. 4A-4D illustrate the lobed artificial disc device 36 implanted between the adjacent upper and lower vertebrae 20 and 22. In the view of Fig. 4C, the disc device 36 is employed with the annulus 65 kept intact, and

in the other view, the annulus 65 is removed with the disc device 36 implanted. To maintain the annulus 65, the disc device 36 is inserted through an incision in the annulus 65 which may be repaired once the device 36 is implanted. In this instance, the device 36 reinflates the annulus 65 keeping it taut and relieves the compressive loading on the annulus 65. The other artificial disc devices described herein can be employed in a like manner to that of device 36.

The annular load bearing body portion 45 of the device 36 has an outer peripheral surface 66 (Fig. 3C) with a generally convex configuration similar to the convex curved configuration at the corresponding radially outer location of the outer annular bearing 14. In contrast, the corresponding surface 68 of the load bearing portion 46 of the device 38 shown in Fig. 5C has a grooved or concave configuration to form thinned upper and lower flange rims 70 and 72 thereof. The above-described construction for the bearing 46 as shown in Fig. 5C provides it with greater flexibility as the flanges 70 and 72 are better able to flex toward each other under compressive loading and thus are optimized from a shock absorption standpoint. In particular, by having the flanges 70 and 72 extending around the entire circumference of the bearing 46, compressive loads taken locally by the bearing 46 such as due to bending of the spine in a particular direction will cause the portions of the flanges 70 and 72 thereat to flex toward each other about the concave peripheral surface 68 while the remainder of the disc 46 including the unloaded portions of the flanges 70

and 72 will remain substantially undeformed. Once this loading is removed, the bent portion of the flanges 70 and 72 can resiliently flex back to their illustrated substantially undeformed configuration. In this manner, the flanges 70 and 72 better permit directional deformation of the bearing 46.

Optionally, upper and lower annular layers including the flanges 70 and 72 can be provided of harder material than a more flexible core material of the bearing body 43 for optimized wear resistance at the interfaces with the vertebral surfaces 20a and 22a and also for improved shock absorbing properties for the device 38a. For instance, the wear layers can be of hard polyethylene while the core of the body 43 would be of more flexible, e.g. elastomeric, cushioning material.

Referring next to Figs. 6A-6F, another artificial disc device 74 in accordance with the invention is illustrated. The artificial disc device 74 is similar to the device 10 of Figs. 1A-1E in that it includes a central ball bearing 76 such as of ceramic material or stainless steel or titanium metal and alloys thereof or having carbon fiber or other biocompatible materials therein and including projecting arc surface portions 78 and 80 for seating in the indents 27 and 29 in the vertebral surfaces 20a and 22a, as previously described. The device 74 is modified over device 10 in that rather than having a doughnut shaped bearing 14, the device 74 includes a pair of annular plates or discs 82 and 84 such as of a metallic material vertically spaced along central axis 86 that extends through the central openings 88

and 90 formed in the respective discs 82 and 84 in which the ball bearing 76 is received. As shown, the disc openings 88 and 90 are of a maximum diameter that is slightly less than that of the diameter of the ball bearing 76 such that when the arcuate surfaces 83 and 85 about the openings 88 and 90 are in close fit with the outer ball surface 92 and the discs 82 and 84 are in a generally parallel orientation, the discs 82 and 84 will be spaced by a gap 94 therebetween.

With the device 74 loaded and the confronting vertebral surfaces 20a and 22a engaging and pushing on the discs 82 and 84, they will shift and pivot relative to each other and axis 86 closing the gap 94 at certain locations thereabout and opening it at others. As such, it is the upper surface 82a and lower surface 84a of the respective upper and lower discs 82 and 84 that are the major load bearing surfaces for the device 74. As shown, these surfaces 82a and 84a can be contoured so that the respective discs become thicker as extending from the periphery toward the respective openings 88 and 90 of the discs 82 and 84.

In an alternative form, a resilient and flexible cushioning material 95 can be attached between the discs 82 and 84. The material 95 will keep the unloaded discs 82 and 84 in the illustrated, generally parallel orientation, but also allow them to undergo relative shifting under compressive loading. In this regard, the material 95 is selected so that it can resiliently expand and contract as the discs 82 and 84 shift and tilt or pivot with respect to each other. Alternatively, the unloaded discs 82 and 84 could be canted to a non-

parallel orientation relative to each other to provide the disc device 74 with a wedged configuration similar to the previously-described device 10a.

Accordingly and as described above, as the spine and particularly the vertebrae 20 and 22 exert compressive loading on the discs 82 and 84, they can shift relative to one another so they are better able to conform to the position of the vertebrae 20 and 22 as they shift with spine movement. For example, if the patient bends anteriorly, the upper disc 82 can tilt relative to the axis 86 so the gap spacing 94 between the discs 82 and 84 can be greater at the rear portion than at the forward portions thereof. In a like manner, if the patient bends their spine posteriorly, then the upper disc 82 can pivot about axis 86 such that the gap spacing 94 can be greater at the forward portions relative to the spacing at the rear portions. In each instance described above, there will usually be some tilting of the lower disc 84 as well although not to the same degree as that of the upper disc 82 so that their tilting movements relative to the axis 86 generally will correspond to that of the upper and lower vertebrae 20 and 22 and the surfaces 20a and 22a thereof relative to the axis of the spine.

The discs 82 and 84 can have a plan configuration akin to that of the lobed bearing 46, or alternatively they can be oval or ellipsoidal. As shown in the plan view of Fig. 6D, the configuration of the discs 82 and 84 includes a larger recessed or concave area 94 as compared with the corresponding recess area 52 of the ring bearing 46. Further, the curvature of the remainder of the disc periphery 96 varies from a convexly curved portion 98

opposite the recessed area 94 to straighter opposite sides 100 and 102 on either side of the recessed area 94.

Turning to Figs. 7A-7C, an alternative construction for the central bearing 39 is shown. In this version, a pair of opposing domes 104 and 106 are provided which ride on an inner bearing portion 107 similar to previously-described ball bearing portion 44, albeit modified to accommodate the projecting post 108 and hub 110, which are described below.

The hub 110 can have a recess 112 which can engage against the distal curved end 114 of the post 108 to resist the compressive forces that otherwise would push the dome shells 104 and 106 further toward each other. More particularly, the dome shell 104 has an end edge 116 and the post 108 extends centrally from the shell 104 along axis 118 so that it projects beyond the edge 116. Likewise, the shell 106 includes an end edge 120 beyond which the hub 110 can project along the central axis 118 so that it is in alignment with the post 108. The post 108 and hub 110 have their respective sizes coordinated so that they define a limit at which spacing 122 between the dome shells 104 and 106 cannot be exceeded with the end edges 116 and 120 extending generally parallel to each other. In this manner, unlike the previously described central bearing assemblies 39 that rely on the stiffness or resilience of the polymeric spherical bearing portion 44 to resist compression of the dome shells 40 and 42, the dome shells 104 and 106 which are preferably of a harder material such as metal employ the

cooperating integral post 108 and hub 110 for limiting the maximum compression that can occur therebetween. As is apparent, under normal conditions, the post 108 and hub 110 will be spaced or only lightly engaged so that they do not bear the loads generated between the vertebrae 20 and 22.

As mentioned above and referencing Figs. 8A-8E, the central or inner bearing portion 107 is modified so that the post 108 and hub 110 can project therethrough. As seen in the cross-sectional view of Fig. 8E, the bearing portion 107 has an axial through opening 124 having reversely configured upper and lower frustoconical surface portions 124a and 124b into which the post 108 and hub 110 extend, respectively. The surface portions 124a and 124b taper from the largest size of the opening 124 at the dome surfaces to the smallest size of the opening 124 at the center of the ball bearing portion 107. This provides the domes 104 and 106 with freedom of movement about the ball bearing portion 107 allowing the post 108 and hub 110 to rock back and forth until the dome ends 116 and 120 engage the web wall 62 without encountering interference from the surface portions 124a and 124b, respectively.

In Fig. 9, a further variation of the central bearing assembly shown in Figs. 8A-8E is illustrated. In this version of an artificial disc device 125, instead of having the apertured central bearing portion 107 that is integrally connected to the web wall 62, upper and lower inner bearing rings 126 and 128 are provided supported by an inner extension 130 of the web wall 62

that extends therebetween. The rings 126 and 128 each have an outer arcuate bearing surface 126a and 128a on which the dome shells 104 and 106 ride. The rings 126 and 128 can also translate along the web wall 62 to provide for lateral movement of either or both dome shells 104 and 106 during articulation of the spine such as when the patient bends their spine in flexion or extension. In this manner, the device 125 provides for an even greater range of motion than the previously described devices as there are now three shifting interfaces including the innermost interface between the rings 126 and 128 and web wall 62 enabling the dome shells 104 and 106 to reciprocate therealong. At the same time, the shells 104 and 106 may be rotating in the indents 27 and 29 and rotating about the rings surfaces 126a and 128a, such as in the previously-described devices. For wear resistance, the rings 126 and 128 can be of a hard polyethylene material while the web wall 62 is preferably of a more flexible or pliant material for shock absorption purposes. For sliding of the rings 126 and 128 on the web wall 62, it can be coated with a harder material or have washers of metallic or a like hardness material attached to upper and lower surfaces thereof to reduce the friction coefficient with the rings 126 and 128 sliding thereon.

Referring next to Figs. 10A-10H, an alternative artificial disc implant device 132 is illustrated in which there is an enlarged, central bearing member 134 and an outer bearing member 136 which share the compressive loads generated between the vertebrae 20 and 22 during typical spine movements. The central bearing member 134 has a post body 138 that is

axially elongated such that upper and lower arcuate bearing surfaces 140 and 142 generally extend beyond corresponding upper and lower bearing surfaces 144 and 146 formed on annular body 148 of the outer bearing member 136, similar to the previously-described disc implants herein.

5 The outer bearing body 148 has a central through opening 150 that is bounded by a cylindrical inner surface 152 in close confronting relation to outer side surface 154 on the post body 138. To provide optimized controlled resiliency of the shape retentive bearing body 148, through apertures 156 can be formed at selected locations extending axially
10 therethrough, as shown in Fig. 10D. These apertures 156 provide an increase in the normal compressibility or coefficient of restitution of the material, e.g. plastic, of the bearing body 148. Based on the position, pattern and/or density of the through apertures 156, the flexibility or compressibility of the body 148 can be increased or decreased in a localized
15 fashion. Of course, these apertures 156 could be employed in the other disc implants and specifically the bodies of the outer bearings thereof in a like fashion. Similarly, the previously-described liquid or gel material, e.g. Hydrogel, used in the outer bearing body 17 could also be provided in the apertures 156 so that they do not extend all the way through the body 138
20 and instead serve as chambers for the visco-elastic material therein to vary compressibility of the body 148.

For instance and as shown in the plan view of Fig. 10A, the frequency of the apertures 156 can be increased in a radially outward direction from

the central opening 150 to the periphery of the bearing body 148 so that in a like fashion the body 148 can be more easily compressed toward the periphery thereof. Alternatively, the size or diameter of the holes 156 can vary such as by having, for example, smaller size apertures 156a closer to the central opening 150, larger size apertures 156b closest to the radially outer periphery of the body 148, with apertures 156c having sizes intermediate those of apertures 156a and 156b generally disposed therebetween, as shown in Fig. 10E. As is apparent, by selective spacing and/or sizing of the aperture 156, the bearing body 148 can be made to be more or less flexibly resilient at precise locations thereabout. In this manner, the bearing body 148 can be stiffer in locations where load bearing is more critical and more compressible at positions where shock absorption is more important. It is also anticipated that the apertures 156 will provide stress relief for the load bearing body 148 so as to increase the life thereof.

As seen in the cross-sectional views of Figs. 10D and 10H, the post body 138 preferably is provided with a recess in its surface 154 such as annular groove 139 formed approximately midway along the body length between the bearing surfaces 140 and 142 thereof. By way of this groove 139, there is a gap 155 that is formed between the confronting bearing surfaces 152 and 154. When the resilient body 148 of the outer bearing 136 is compressed, the gap 155 provides space into which the resilient material of the body 148 can deform and expand laterally.

An alternative disc device 175 is shown in Figs. 11A-11D having upper and lower disc plate members 176 and 178 with there being a load bearing member 180 therebetween. However, unlike prior devices, the device 175 like other devices described herein allows for relative movement between the vertebrae 20 and 22 and the respective vertebral engaging members 176 and 178. The plate members 176 and 178 have arcuate vertebral engaging surfaces 182 and 184 formed thereon having a gradual curvature or slope extending from the outer periphery up toward central axis 186 of the device 175. As the surfaces 182 and 184 approach the axis 186 they begin to extend more axially than radially to form center projections 188 and 190. These projections 188 and 190 are shown in Figs. 11C and 11D as being provided with a tip or point end 191 and 193 for piercing into the vertebral bone locating the device 175 implanted between the vertebrae 20 and 22 although they also could simply be curved or sloped as shown in Figs. 11A and 11B to serve the same locating function similar to the center arcuate surface portions of previously-described devices.

Accordingly, the surfaces 182 and 184 include radially extending bearing surface portions 182a and 184a that extend radially along the respective facing vertebral surfaces and central, axially extending bearings surface portions 182b and 184b that serve to locate the device 175 while also allowing relative sliding rotation of the vertebrae 20 and 22 thereabout and specifically 360° about device axis 186 since the plate members 176 and 178 are not fixed to the respective vertebrae 20 and 22. The center surface

portion 182b and 184b only resist lateral sliding of the plates 176 and 178 by fitting in correspondingly shaped recesses or openings in the vertebral facing surfaces 20 and 22a and otherwise are not fixed or fastened thereto.

As shown, the member 180 has a spherical ball configuration. The plates 176 and 178 have arcuate recessed surfaces 192 and 194 opposite their surfaces 182 and 184 and in which the ball member 180 seats. The ball member 180 can be of a harder material, e.g. steel, than the softer disc plate members 176 and 178. The materials for the members 176-180 is preferably selected for low frictional resistance to relative sliding movement therebetween to allow rotation of the members 176-180 such as when the spine is twisted and to allow relative sliding between the plate members 176 and 178 and ball 180 such as when the spine is bent in flexion and extension with the plates 176 and 178 pivoting with respect to each other. In this manner, the device 175 is bi-polar since there are two shifting interfaces thereof, i.e. between the plates 176 and 178 and the vertebrae 20 and 22 and between the ball 180 and the plates 176 and 178.

Figs. 11E-11H are views of another device 175' similarly constructed to device 175 including upper and lower plates 176 and 178 with a ball bearing 180 therebetween. The device 175' also includes an annular member 196 that extends about the ball bearing 180 with the plates 176 and 178 engaged against upper and lower surfaces 196a and 196b thereof. The annular member 196 acts as a shock absorber and can be formed of an

elastomeric or other resilient material, or be a resilient membrane filled with saline.

As is apparent, the various forms of artificial disc devices disclosed herein rely on both a center bearing portion and an outer, annular bearing portion extending about the center bearing portion to provide implants that resist migration without relying on disc fixing mechanisms such as intrusive bone fasteners, clamps and the like while also avoiding subsidence problems about the center bearing portion. To this end, the upper and lower arcuate surfaces of the center bearing or bearing portion or bearing assembly seat in correspondingly shaped recesses 27 and 29 in the vertebral surfaces 20a and 22a to locate the artificial disc device between the vertebrae 20 and 22. The interface between the center bearing surface portions and the recesses 27 and 29 is preferably a sliding one, i.e. not fixed, to substantially provide the vertebrae with their normal range of motion relative to each other with the discs implanted therebetween. And because of the enlarged axial spacing of the surface portions relative to the outer bearing portion, be they formed on separate components such as the dome shells or on a single part such as center ball or post bearings, the convex curvature of the center surface portions seated in the concave recesses provides resistance against migration or lateral shifting of the device out from between the vertebrae.

Extending about these axially projecting center bearing surface portions are outer bearing surface portions that also extend radially

outwardly therefrom, generally with a more gradual curvature or with a flat configuration. As shown, the outer bearing surface portions extend so that their radial outer ends are close to the periphery of the respective vertebral bodies thereabove and therebelow. Accordingly, the upper outer bearing surface portion is generally lower than the axially projecting upper center bearing surface portion, and they form a juncture at which the direction in which the surface portions of the disc device for engaging the vertebrae changes or transitions from one extending more axially to one extending more radially. This juncture is a direction transition area and does not necessarily mean that the surface portions are joined thereat, such as can be seen with the previously-described ball bearing 12 and ring bearing 14 which are separate components with the ring bearing 14 extending annularly around the ball bearing 12 so as to allow for relative movement therebetween. Similarly, the lower outer bearing surface portion is generally higher than the axially projecting lower center bearing surface portion, and at their juncture the direction of the vertebral engagement surface portion of the device also changes as described above with respect to the upper vertebral engagement surface portions. In this manner, these radially extending outer surface portions limit the ability of the vertebrae or their attached end plates to subside around the center bearing. If there is any subsidence, its extent is limited by the axial spacing of the upper and lower outer bearing surface portions. In other words, in the area taken up by the artificial disc, the spacing of the upper and lower vertebrae can not

be less than the spacing between the outer bearing surface portions, thereby limiting subsidence problems accordingly.

In another version of a disc device 200 in accordance with the above principles, upper and lower arcuate center bearing surface portions 202 and 204 that are convexly curved are provided for locating the device 200 between adjacent vertebrae in corresponding arcuate concave recesses formed therein. Upper and lower outer bearing surface portions 206 and 208 extend annularly about respective center bearing surface portions 202 and 204 and limit subsidence between the vertebrae about the center bearing portion 210 of the device 200. The upper surface portions 202 and 206 are formed integrally on an upper plate member 212, and the lower surface portions 204 and 208 are formed integrally on a lower plate member 214. The plate members 212 and 214 can be of a hard biocompatible material such as titanium coated with a pyroletic carbon. Like previously-described discs, the center bearing surface portions 202 and 204 are spaced by an axially greater distance than the outer bearing surface portions 206 and 208, and they have a smaller radius of curvature than the more gradual curvature of the surface portions 206 and 208. As such, as the vertebral engaging surface portions extend away from the disc axis 216, there is upper and lower junctures 218 and 220 where the direction and configuration of the surface portions undergo an abrupt change from one where the surface portion 202 or 204 extends more axially versus one where the surface portion 206 or 208 extends more radially to provide subsidence resistance

about the center bearing 210. To this end, the plate members 212 and 214 include respective small, axial projections 213 and 215 that are centrally disposed relative to disc axis 216 and on which the respective center bearing surface portions 202 and 204 are formed.

5 As part of annular, outer bearing portion or assembly 222 extending about the center bearing assembly 210, an annular load bearing portion or member 224 is provided axially between the upper and lower bearing plates 212 and 214. The member 224 is preferably of a resilient material such as an elastomeric or resiliently compressible polymeric material, e.g.
10 polyurethane and silicone combination, or a hydrogel material, for taking loads that are generated between the vertebrae during normal spinal movements. The member 224 can also comprise a resilient membrane that is filled with saline for this purpose. The annular member 224 has an axial thickness sized to maintain the plates 212 and 214 spaced axially by an
15 anatomically correct distance from each other for engaging the vertebrae and keeping them properly spaced. At the same time, the resilient material of the load bearing member 224 allows the plates 212 and 214 to shift or deflect relative to each other during dynamic relative movements of the spine vertebrae 20 and 22 such as when the spine is being twisted and bent
20 as in flexion or extension movements. For example, at one end of the disc 200, the plates 212 and 214 may be pivoting toward each other compressing the member 224 therebetween while at a generally diametrically opposite end the plates 212 and 214 will pivot or shift away from each other allowing

for expansion of the resilient material of the member 224 in this area between the plates 212 and 214.

The annular bearing member 224 can be a composite to include a harder low friction wear coating on its upper and lower surfaces to allow the facing lower and upper surfaces of the respective upper and lower bearing plates 212 and 214 to minimize wear in this interface area such as when compressional and/or torsional forces are applied therebetween. Alternatively, upper and lower annular washers or wear plates 226 and 228 can be inserted in the interfaces between the upper bearing plate 212 and the load bearing member 224 and the lower bearing plate 214 and the load bearing member 224 to allow the plates 212 and 214 to have a low friction surface in engagement therewith.

The annular configuration of the load bearing member 224 of the outer bearing portion 222 forms an interior central space 230 in which a bumper or plug member 232 is provided as part of the center bearing portion 210 of the device 200. The bumper member 232 fits somewhat loosely in the interior space 230 and is of a harder material having a higher modulus of elasticity than the outer bearing member 224. Thus, the plug member 232 is operable during high impact loading on the vertebrae to keep the annular member 224 from deforming too much and overloading. In normal loading conditions, there is a spacing between the upper plate member 212 and the bumper member 232. The harder plug member 232 allows the annular member 224 to be softer so that its cushioning function

between the vertebrae can be maximized. At the same time the material of the member 224 needs to be of sufficient stiffness or resiliency so as to be substantially shape retentive for maintaining stability between the vertebrae over millions of cycles and without experiencing undesirable material creep or plastic deformation due to the heavy loading it will undergo.

As can be seen in Figs. 12A and 12C, the plates 212 and 214 have respective arcuate projections 234 and 236 that extend toward each other in the interior space 230. The plug member 232 has upper and lower arcuate recesses 238 and 240 concavely configured to mate with the convex configuration of the arcuate projections 234 and 236, respectively. The relative sizing of the space 230 and the plug member 232 therein is such that when the plug member 232 rests on the lower plate 214 via seating of the projection 236 in the recess 240, there will be an axial gap 242 between the plug 232 and the upper plate 212 and specifically the respective surface 238 and projection 234 thereof. Accordingly, the annular member 224 has a greater axial thickness than the plug member 232. The space 230 has a larger diameter than the plug member 232 so that there is a generally lateral space between the inner surface 224a of the annular member 224 and the plug member 232 allowing for lateral deformation of the resilient member 224 when loaded. When the vertebrae are overloaded such as due to shock or high impact loads, the normal loading ring member 224 is compressed taking up the axial gap 242 such that the projection 234 engages the harder plug member 232 in the recess 238 thereof. In this manner, further

compression and overloading of the resilient member 224 is avoided. Also, engagement of the projections 234 and 236 in their recesses 238 and 240 resists relative lateral shifting between the plates 212 and 214, and the annular member 222.

5 It is also contemplated that the annular member 224 and plug member 232 could be integrally formed with one another, although having the members 224 and 232 as separate components is the preferred form for the present disc device 200.

10 As best seen in Fig. 12C, the arcuate projections 234 and 236 are larger than the respective arcuate surface portions 202 and 204. The projections 234 and 236 are centrally disposed relative to axis 216 and extend radially for a greater distance on either side of axis 216 than do the arcuate surface portions 202 and 204 so that there is a greater bearing surface interface between the plate projections 234 and 236 and the plug member 232 than between the locating surface portions 202 and 204 and the vertebrae. As such, when the plug member 232 is loaded, it provides relatively large bearing surfaces for the plates 212 and 214, and also allows for pivoting between the plates 212 and 214 with the plate central projections 234 and 236 sliding in respective recesses 238 and 240 and with compression and expansion of generally diametrically opposed portions of the member 224 depending on the exact location of the loads placed on the device 200. Alternatively, the surface portions 202 and 204 can be similarly

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sized to the projections 234 and 236 or even larger for maximizing the bearing surface area they provide between the device and the vertebrae.

In Figs. 12D and 12E, the disc device 200 is shown with modifications including an annular sheath 244 that extends about the outer periphery of the device 200. The sheath 244 includes upper and lower lips 246 and 248 and that grip around and onto the upper and lower surfaces 206 and 208, respectively, of the outer bearing assembly 222 to hold the device 200 in its assembled form for implantation. Alternatively, a bag completely encasing the device 200 could be employed. Also, a retaining structure, generally designated 250, can be provided between the plates 212 and 214 and the annular member 224 for resisting relative lateral shifting between the plates 212 and 214, and the member 222, as well as resisting relative rotational shifting therebetween for keeping these disc components aligned.

Projecting posts 252 and 254 can project down from the underside of the upper plate 212, and posts 256 and 258 can project up from the upper side of the lower plate 214. Corresponding aperture pairs 260 and 262 can be formed in the upper and lower surfaces of the annular bearing member 224 for receiving the respective post pairs 252, 254 and 256, 258 therein, as can be seen in Fig. 12E. Alternatively, the location of the posts and apertures could be reversed. In another alternative form of retaining structure 250, upper and lower annular grooves 261 (upper groove 261 shown in ghost in Fig. 12D) can be formed in upper and lower surfaces of the annular bearing member 224 for receipt of corresponding upper and lower raised ridges

formed on the resilient annular member 224. Since the plan shape or configuration of the plates 212 and 214 and member 224 are other than circular, it is desirable for the ridges and grooves to be similarly configured so that relative rotational sliding as well as translational or lateral sliding
5 between these components is resisted. Again, the components on which the cooperating grooves and ridges are formed can be reversed from that described above.

Instead of the posts/recess or groove/ridge structure 250, the structure 250 can be provided at the periphery of the device 200, as shown
10 in Fig. 12F. The upper plate 212 includes a downwardly extending peripheral lip projection 263, and the lower plate 214 includes an upwardly extending peripheral lip projection 264. The resilient member 224 is provided with peripheral grooves 266 and 268 in which the lips 262 and 264 extend so as to restrain the member 224 against lateral and rotational
15 shifting relative to the plates 212 and 214.

Figs. 12G-12I show device 200 modified to include upper and lower recessed channels 270 formed in the upper and lower surfaces of the annular member 224 that extend from the inner, axially extending surface 224a to the outer peripheral surface 224b of the member 224 to form
20 openings at each surface. In this way, the interior space 230 in which the plug member 232 is received communicates with the space external to the device 200 via the flowpaths provided by the channels 270. Thus, the channels 270 allow for fluid flow into and out from the device between the

plates 212 and 214 and the annular member 224. The channels 270 also keep vacuum conditions from developing in the space 230 as its volume continually varies with vertebral movements and thus the channels 270 serve as a vacuum breaker for the device 200. The channels 270 can be
5 provided in a radial pattern so that there are several pairs of channels 270 extending in radially opposite directions from the center space 230, as best seen in Fig. 12H.

While there have been illustrated and described particular embodiments of the present invention, it will be appreciated that numerous
10 changes and modifications will occur to those skilled in the art, and it is intended in the appended claims to cover all those changes and modifications which fall within the true spirit and scope of the present invention.

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We Claim:

1. A spinal artificial disc device for being implanted between adjacent axially spaced upper and lower vertebrae, the artificial disc device comprising:

5 upper and lower central bearing surface portions having an arcuate, generally axially extending configuration for projecting toward and slidably engaging against respective facing vertebral surfaces;

upper and lower outer bearing surface portions that generally extend radially outward from corresponding upper and lower central bearing surface portions for projecting along the vertebral surfaces,

10 the central bearing surface portions being axially spaced by a greater distance than the radially outer bearing surface portions with the central and outer bearing surface portions sharing compressive loads generated during spinal movements for minimizing vertebral subsidence about the axially enlarged central bearing surface portions; and

15 junctures between the upper and lower central bearing surface portions and the corresponding upper and lower outer bearing surface portions at which the bearing surface portions change directions from extending generally axially on the central bearing surface portions to extending generally radially on the outer bearing surface portions.

20 2. The artificial disc device of claim 1 including:

a central ball bearing having an outer spherical surface that includes the central arcuate bearing surface portions; and

an outer annular bearing having the outer bearing surface portions formed thereon and including an inner side surface facing the central bearing spherical surface and being configured to allow relative rotation between the central spherical bearing and the annular bearing.

3. The artificial disc device of claim 2 wherein the inner side surface has a flat configuration extending generally axially and radially spaced from the spherical surface or an arcuate configuration having a radius of curvature similar to that of the spherical surface.

4. The artificial disc device of claim 1 wherein the upper central and outer bearing surface portions are formed on an upper plate member and the lower central and outer bearing surface portions are formed on a lower plate member.

5. The artificial disc device of claim 4 including an annular member between the upper and lower plate members of a predetermined resilient material for providing a cushioned support therebetween, and a plug member about which the annular member extends having an axial thickness less than that of the annular member and being of a predetermined material

that is harder than the resilient material of the annular member to limit overloading thereof.

6. The artificial disc device of claim 1 including:

5 a bearing body having a central enlarged arcuate bearing portion, and an outer bearing portion on which the outer bearing surface portions are formed; and

upper and lower dome shells configured to slide on the arcuate bearing portion and having the respective upper and lower central bearing surface portions thereon.

7. The artificial disc device of claim 6 wherein the enlarged arcuate bearing portion has a spherical configuration.

15 8. The artificial disc device of claim 1 wherein the central arcuate surface portions have a greater curvature than the outer bearing surface portions.

9. The artificial disc device of claim 8 wherein the outer bearing surface portions are curved, flat, or contoured.

10. The artificial disc device of claim 1 wherein the upper and lower outer bearing surface portions are formed on an outer bearing portion

which has radially inner surfaces adjacent the central bearing surface portions configured to allow relative movement therebetween.

11. The artificial disc device of claim 10 wherein the outer bearing
5 portion includes a body having an annular portion, and

a central bearing portion with the outer bearing annular body portion extending about the central bearing portion and central bearing surface portions.

10 12. The artificial disc device of claim 11 wherein the annular outer bearing portion and central bearing portions are distinct members.

13. The artificial disc device of claim 11 wherein the central bearing
15 portion includes a central body portion integral with outer bearing annular body portion.

14. The artificial disc device of claim 13 wherein the central and annular body portions include a radially extending web wall that spaces said body portions by a predetermined gap spacing; and

20 upper and lower shells of the central bearing portion which have the respective upper and lower arcuate central surface portions thereon with the shells and central body portion being configured to permit sliding of the shells on the central body portion.

15. The artificial disc device of claim 1 including an outer bearing
portion extending about the central bearing surface portions and having a
body with the outer bearing surface portions formed thereon, the body of
the outer bearing portion being of a resilient material and the central
5 bearing surface portions being of a material harder than the resilient
material, and

a compression limiter in the body of the outer bearing portion that is
of a material harder than that of the outer bearing portion body to resist
deformation thereof under compressive loads.

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16. The artificial disc device of claim 15 wherein the outer bearing
portion includes an annular body portion, and the compression limiter
comprises a ring embedded in the annular body portion.

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17. The artificial disc device of claim 1 wherein the outer bearing surface
portions each have a perimeter that generally defines one of a heart shape
and an oval shape.

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18. The artificial disc device of claim 1 including an outer bearing
portion extending about the central bearing surface portions and having the
outer bearing surface portions formed thereon, and

a cushioning material disposed axially intermediate the outer bearing
surface portions.

19. The artificial disc device of claim 18 wherein the outer bearing portion comprises upper and lower annular plates having the respective upper and lower central bearing surface portions formed thereon, and the cushioning material extends between the plates to bias the plates apart and allow resilient shifting of the plates relative to each other during vertebral movements.

20. The artificial disc device of claim 1 including an arcuate central bearing portion and upper and lower shells on which the respective upper and lower central bearing surface portions are formed and which are slidingly supported on the central bearing portion.

21. The artificial disc device of claim 20 wherein the central bearing portion has an axial opening, and at least one of the shells includes a projection extending in the opening to limit axial shifting of the shells toward each other.

22. The artificial disc device of claim 20 wherein the arcuate central bearing portion includes a radially extending wall and upper and lower arcuate bearing rings supported for lateral sliding on the wall disposed therebetween with the shells supported for sliding over the bearing rings to allow for lateral movement of the shells during vertebral movements.

23. The artificial disc device of claim 1 including an outer bearing portion on which the outer bearing surface portions are formed and having a body of a material having a predetermined compressibility and a plurality of apertures in the body to vary the compressibility thereof from the predetermined compressibility.

24. The artificial disc device of claim 23 wherein the body has a predetermined number, arrangement and sizing of the apertures to provide for a controlled variation of the compressibility of the body.

25. The artificial disc device of claim 1 wherein the central bearing surface portions are formed on a central bearing and the outer bearing surface portions are formed on an outer bearing including an annular body that extends about the central bearing, the central bearing having a body that is axially enlarged relative to the annular body.

26. The artificial disc device of claim 25 wherein the central bearing body comprises a generally spherical ball body or an axially elongated post body.

27. The artificial disc device of claim 1 including a bearing body having an axially enlarged central bearing body portion and an outer annular body portion extending about the central body portion, and a web wall integrally interconnecting the central and outer body portions, and upper and lower

shells configured to slide on the central bearing body portion and having the respective upper and lower central bearing surface portions formed thereon.

5 28. An artificial disc device for being implanted between upper and lower vertebrae, the artificial disc device comprising:

 a central bearing for being inserted between the upper and lower vertebrae;

 upper and lower arcuate central bearing surface portions of the
10 central bearing that seat in arcuate recesses formed in the respective facing vertebral surfaces to resist migration of the central bearing from between the vertebrae;

 an annular outer bearing extending around the central bearing so that the outer bearing is kept between the upper and lower vertebrae by the
15 central bearing; and

 upper and lower outer bearing surface portions of the outer bearing extending radially outward from the corresponding upper and lower bearing surface portions of the central bearing for sharing loads therewith to minimize highly localized loading on the bearing surface portions.

20 29. The artificial disc device of claim 28 wherein the outer annular bearing has an inner diameter, and the central bearing is sized to be in

clearance with the annular bearing inner diameter to allow relative movement therebetween.

30. The artificial disc device of claim 28 wherein the central bearing has a generally spherical outer surface including the central bearing surface portions, and the outer bearing includes a central axial through opening in which the central bearing resides and an arcuate inner side surface extending about the opening and facing the spherical central bearing, the arcuate side surface generally having the same radius of curvature as that of the spherical outer surface to allow substantially free rotation of the central bearing seated in the vertebral recesses.

31. The artificial disc device of claim 30 wherein the spherical outer surface has a predetermined diameter, and the outer bearing upper and lower surface portions are axially spaced by a distance that is less than the predetermined diameter so that the central spherical bearing is axially enlarged relative to the annular outer bearing.

32. The artificial disc device of claim 28 wherein the upper and lower surface portions of the central bearing engaged in the vertebral recesses are axially spaced by a greater distance than the upper and lower surface portions of the outer bearing which have an axial spacing sized to maintain

a generally anatomically correct spacing between the upper and lower vertebrae engaged therewith.

33. The artificial disc device of claim 28 wherein the upper and lower surface portions of the outer bearing have an arcuate configuration with a more gradual curvature than the arcuate surface portions of the central bearing for generally conforming to the shape of the facing vertebral surfaces.

34. The artificial disc device of claim 28 wherein the annular outer bearing has a generally wedged configuration including an axially enlarged section between the upper and lower surface portions for optimizing fit of the outer bearing between the vertebrae.

35. The artificial disc device of claim 28 wherein the outer annular bearing extends about a disc axis and comprises upper and lower annular plates with the upper bearing surface portion on the upper plate and the lower bearing surface portion on the lower plate, the plates being axially spaced and extending generally transverse to the disc axis.

36. The artificial disc device of claim 35 wherein the plates have a cushioning material in the axial space therebetween to provide for resilient

shifting of the plates relative to each other and biasing the unloaded plates to a generally parallel orientation thereof.

37. The artificial disc device of claim 36 wherein the central bearing has a generally spherical outer surface including the arcuate surface bearing portions, and the annular plates each include a central opening having a maximum diameter that is less than that of the spherical outer surface for providing the axial spacing of the plates in close fit with the central bearing outer surface.

38. The artificial disc device of claim 28 wherein the outer annular bearing has a central axial through opening, and the central bearing has a body that is axially elongated to extend through the central opening with the upper and lower arcuate surface bearing portions extending axially beyond the corresponding upper and lower outer bearing surface portions.

39. The artificial disc device of claim 38 wherein the outer annular bearing is of resilient material and has an inner surface bounding the through opening, and the axially elongated body includes an outer side surface that is in close confronting relation to the annular bearing inner surface and which has an annular groove to provide a gap between the confronting bearing surfaces into which the resilient material of the outer annular bearing can deform when loaded.

40. The artificial disc device of claim 28 wherein the central bearing is of a harder material than the outer bearing to maintain conformity of the arcuate surface portions in the vertebral recesses.

5 41. The artificial disc device of claim 28 wherein the outer bearing is of resilient material to allow the outer bearing to resiliently deform under compressive loading forces.

10 42. The artificial disc device of claim 28 wherein the outer bearing has an outer wear layer including the bearing surface portions thereof, and an inner cushion portion with the outer wear layer being of harder material than the inner core cushion portion.

15 43. An artificial disc device for being implanted between axially spaced upper and lower vertebrae, the artificial disc device comprising:

upper and lower plate members for engaging facing surfaces of the respective upper and lower vertebrae;

20 a central projection on each of the plate members extending axially and having an arcuate surface thereon for sliding in an arcuate recess in the vertebrae with which the arcuate surface is slidingly engaged;

an annular load bearing member between the plate members for axially spacing the plate members and being of resilient material to allow

shifting of the plate members toward and away from each other with resilient deformation of the annular member; and

a bumper member about which the annular member extends and being of a harder material than the annular member to limit deformation of the annular member.

44. The artificial disc device of claim 43 wherein the annular load bearing member is axially thicker than the bumper member so that there is space between the upper plate member and the bumper member during normal loading conditions of the spine.

45. The artificial disc device of claim 43 including low friction bearing surfaces between the annular member and the plate members to minimize wear therebetween.

46. The artificial disc device of claim 43 wherein the upper plate and lower plate include arcuate central projections extending toward each other, and the bumper member has upper and lower arcuate recesses configured for mating and sliding engagement with the corresponding upper plate and lower plate projections.

47. The artificial disc device of claim 43 including a sheath or bag for holding the plate members, annular load bearing member and bumper member together in assembled form during implantation.

5 48. The artificial disc device of claim 43 wherein the plate members and annular member include retaining structure therebetween that resists lateral and rotational shifting of the plate members relative to the annular member.

10 49. The artificial disc device of claim 48 wherein the retaining structure comprises annular grooves in one of the annular member and the plate members and projections in the other of the annular member and the plate members that extend into the grooves.

15 50. The artificial disc device of claim 43 wherein the annular member defines a central interior space in which the bumper member is loosely disposed and includes openings to the interior space and to exterior of the annular member to provide a flowpath therebetween.

20 51. The artificial device of claim 43 wherein the annular member and at least one of the plate members include a channel therebetween for providing fluid flow between the interior and exterior of the disc device.

52. The artificial disc device of claim 51 wherein the annular member has upper and lower surfaces facing the respective upper and lower plate members, and the channel includes a plurality of radially extending channels formed in the upper and lower surfaces of the resilient annular member.

53. The artificial disc device of claim 43 wherein the resilient material of the annular load bearing member comprises hydrogel.

54. An artificial disc device for being implanted between upper and lower vertebrae, the artificial disc device comprising:

- upper and lower arcuate bearing shells for slidingly engaging against respective facing surfaces of the upper and lower vertebrae;
- a central bearing portion having an arcuate outer surface that supports the shells for sliding thereon to allow for differential shifting between the relative movement of the shells and the engaged vertebrae and of the shells and the central bearing portion during vertebral movements; and
- an annular outer bearing portion extending around the central bearing portion for load sharing with the bearing shells.

55. The artificial disc device of claim 54 wherein the central bearing portion has a generally spherical configuration and the shells have a dome configuration for sliding on the spherical central bearing portion.

5 56. The artificial disc device of claim 55 wherein the spherical central bearing portion has a predetermined diameter, and the dome shells have a maximum diameter that is less than the predetermined diameter.

10 57. The artificial disc device of claim 54 including a web wall that interconnects and spaces the central and outer bearing portions laterally from each other to keep interference between the sliding bearing shells and the outer bearing portion to a minimum.

15 58. The artificial disc device of claim 57 wherein the web wall is integral with the central and outer bearing portions.

20 59. The artificial disc device of claim 54 wherein the central bearing portion and annular outer bearing portion are laterally spaced from each other to form a gap therebetween in which the shells can slide and the annular bearing portion has an inner side surface that extends axially to maximize sizing of the recesses.

60. The artificial disc device of claim 54 wherein annular outer bearing portion is of resilient material and has an outer peripheral surface including upper and lower flanges and a concave groove between the flanges to optimize flexibility of the flanges under compressive loading.

5

61. The artificial disc device of claim 54 wherein the outer bearing portion includes a core of cushioning material for shock absorption and upper and lower bearing surfaces of hard material for wear resistance.

10

62. The artificial disc device of claim 54 wherein the central bearing portion includes an axial through opening, and the shells include projections that extend in the through opening and cooperate to limit compression of the central bearing portion and shifting of the shells axially toward each other.

15

63. The artificial disc device of claim 54 including a web wall interconnecting the bearing portions extending laterally therebetween, and the outer bearing portion includes an inner extension of the web wall and upper and lower arcuate bearing rings that support the respective upper and lower shells for sliding thereon and which are supported for lateral sliding on the web wall including the extension thereof.

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1/22

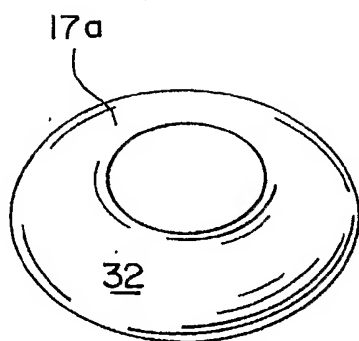


FIG. 1A

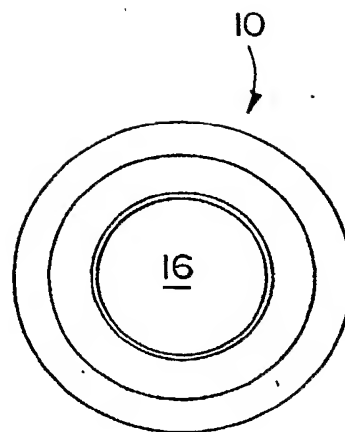


FIG. 1B

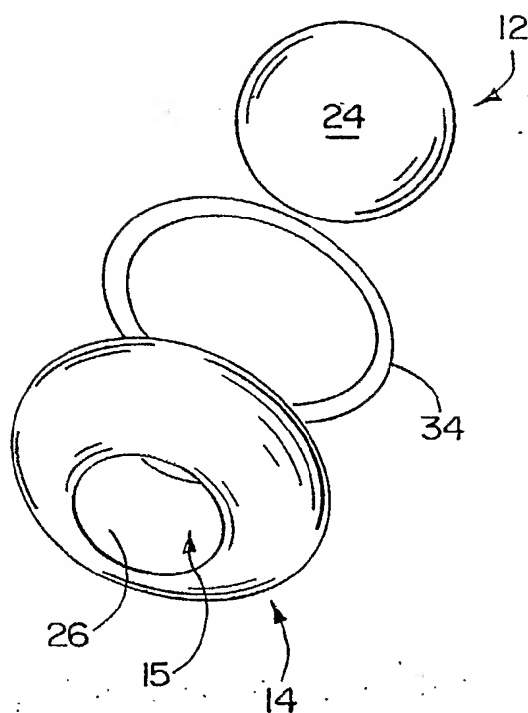


FIG. 1C

2/22

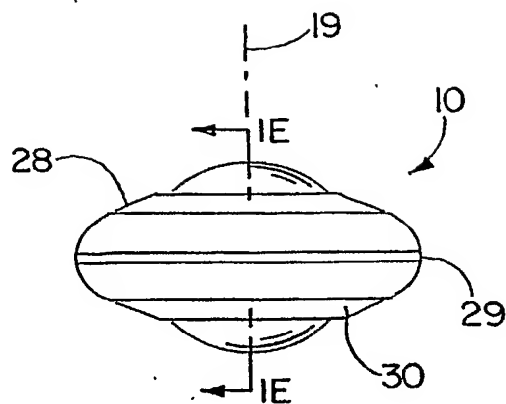


FIG. 1D

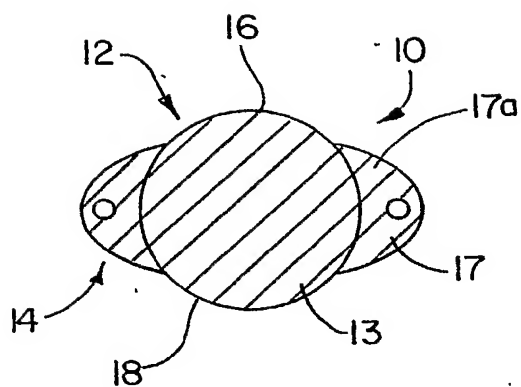


FIG. 1E

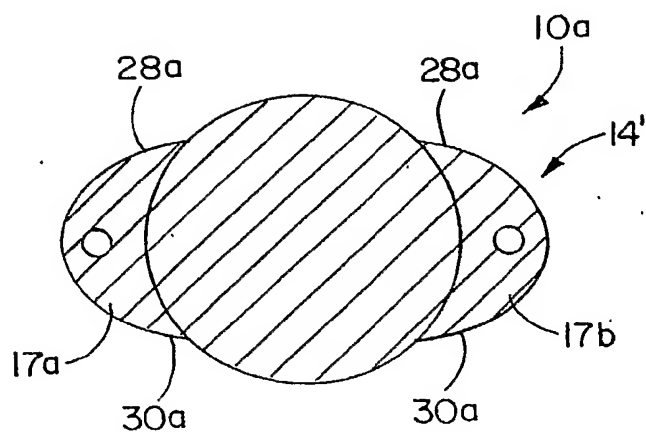


FIG. 1J

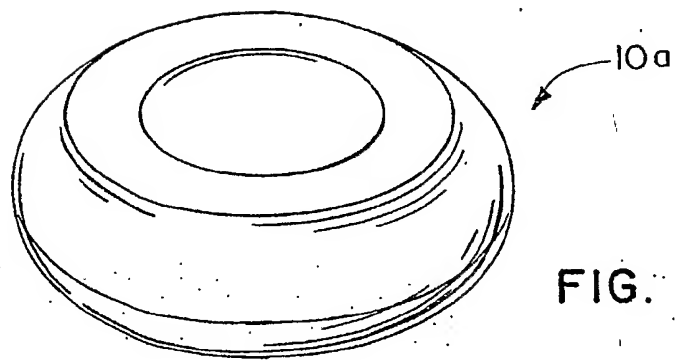


FIG. 1F

3/22

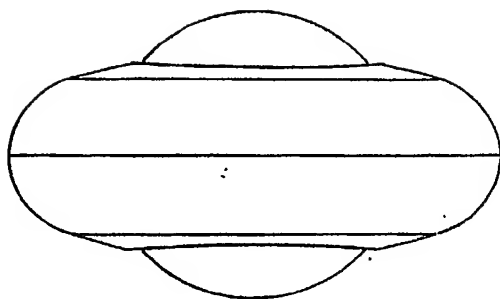


FIG. 1G

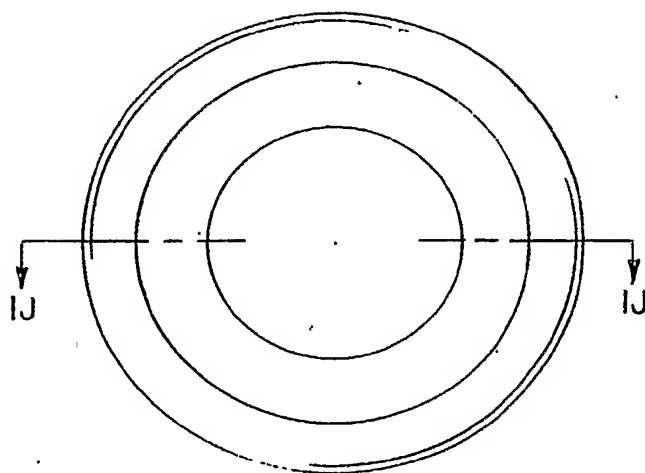


FIG. 1H

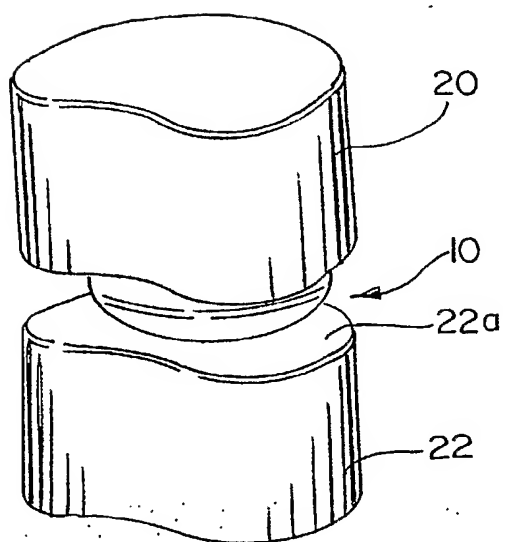


FIG. 2A

4/22

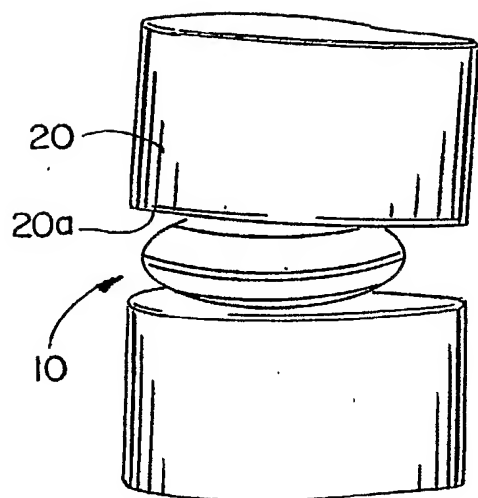


FIG. 2B

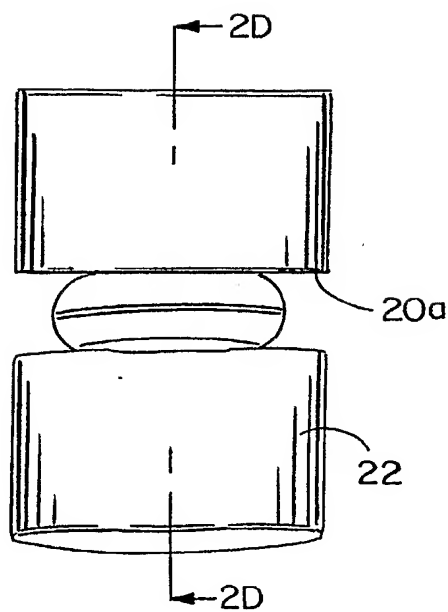


FIG. 2C

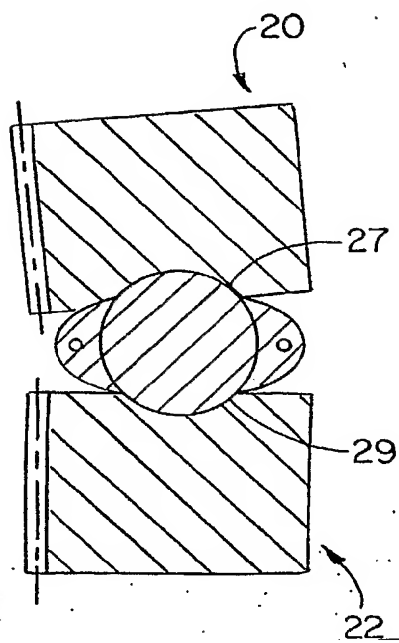
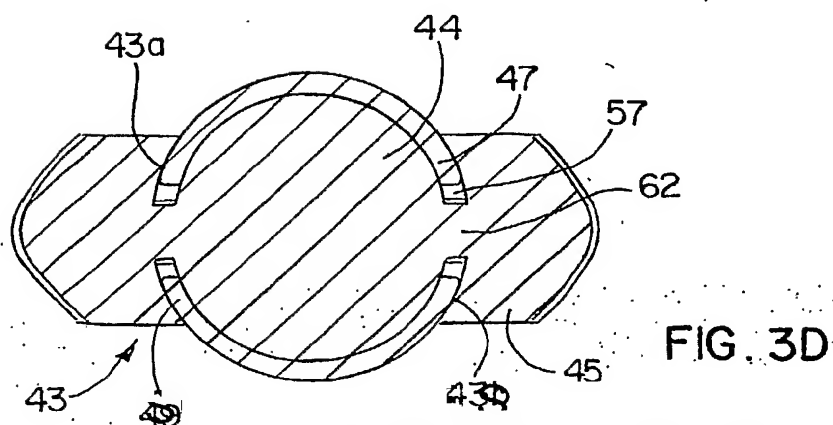
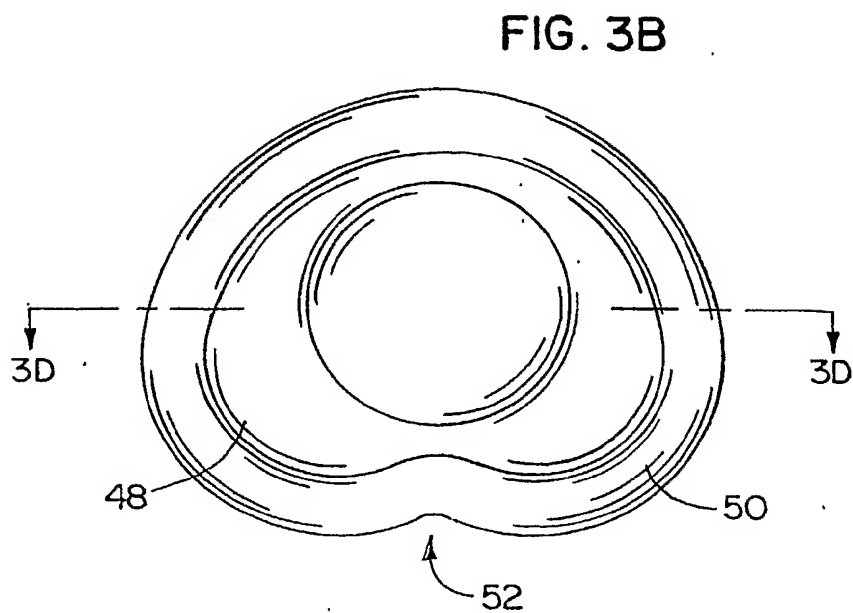
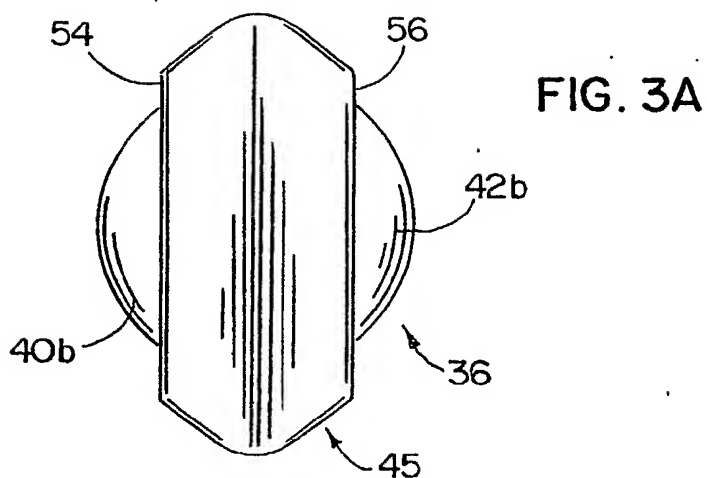


FIG. 2D

5/22



6/22

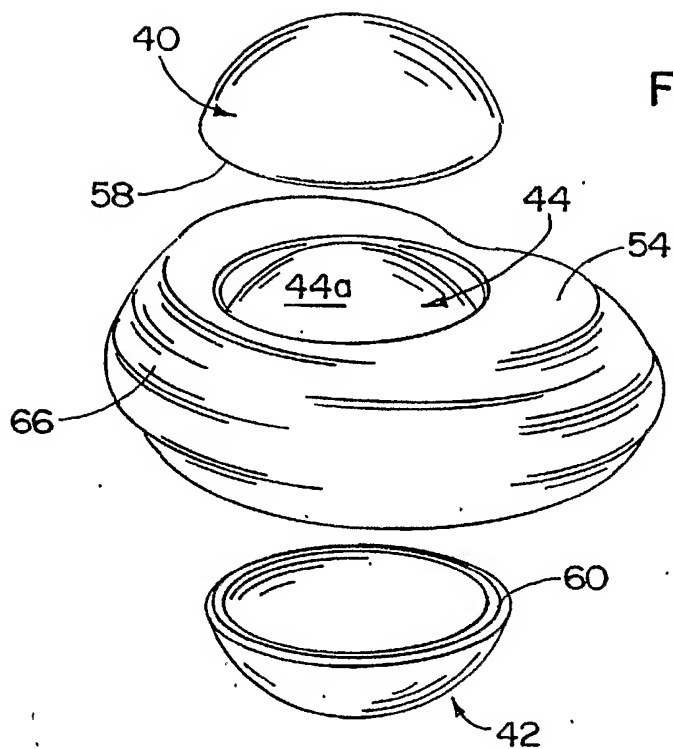


FIG. 3C

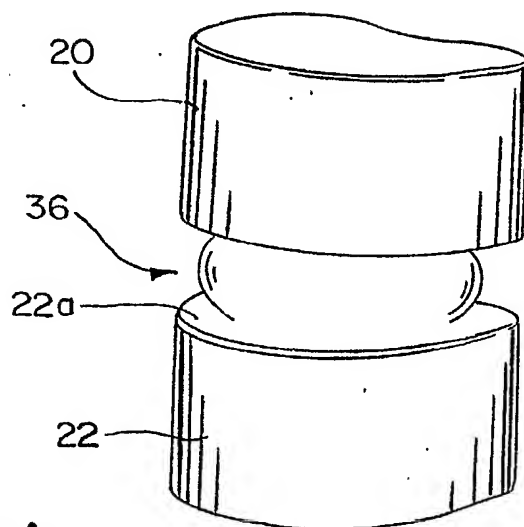


FIG. 4A

7/22

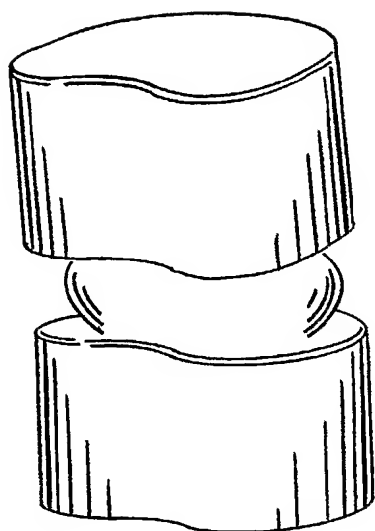


FIG. 4B

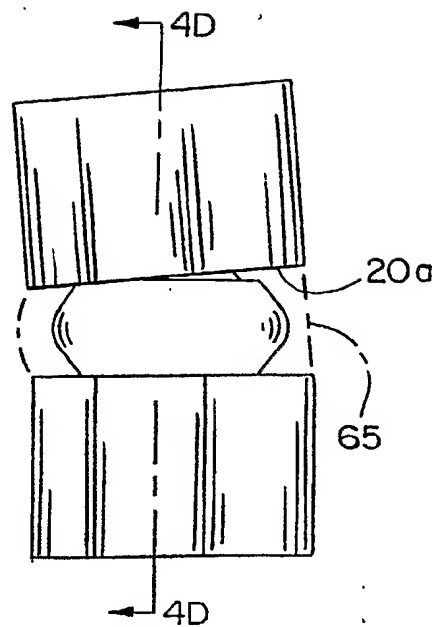


FIG. 4C

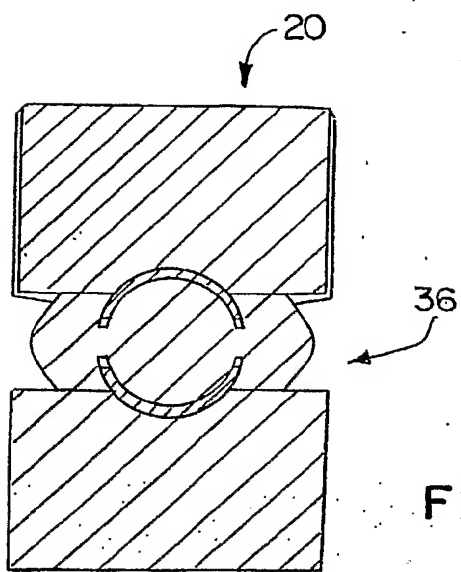


FIG. 4D

8/22

FIG. 5A

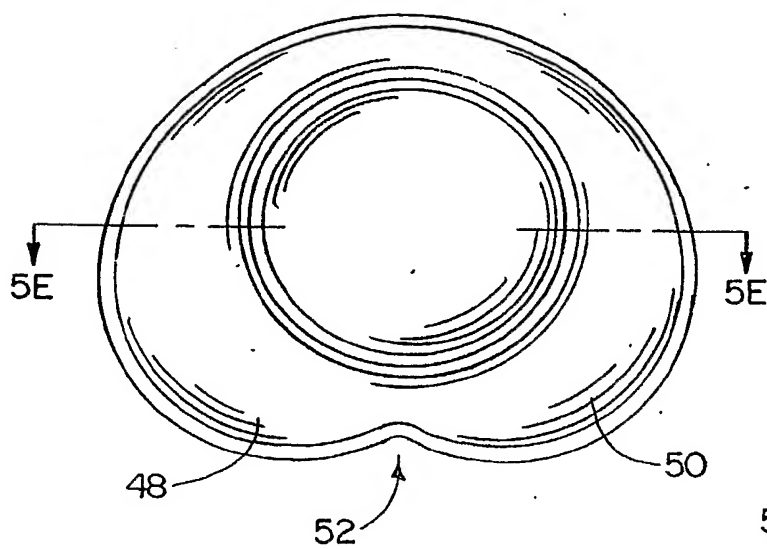
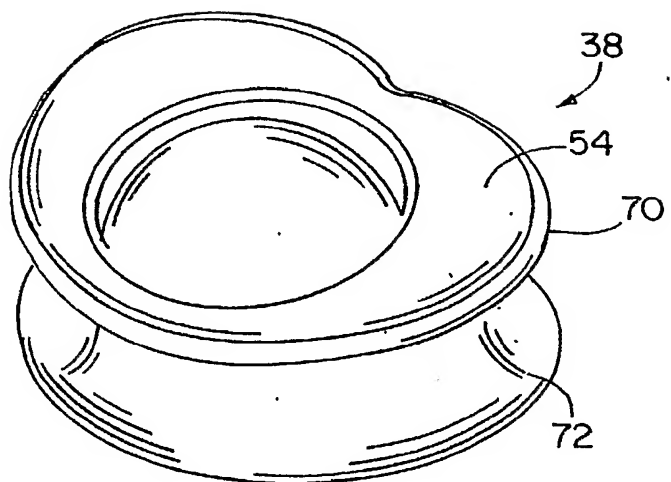


FIG. 5D

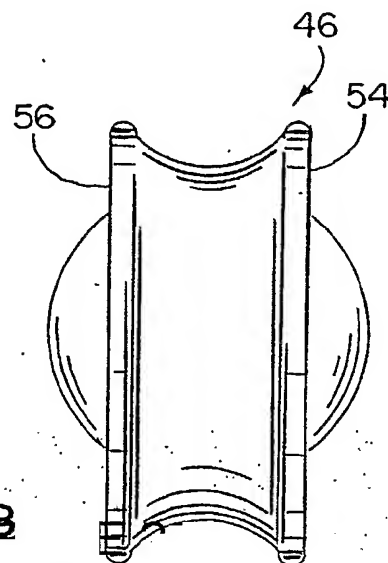


FIG. 5B

9/22

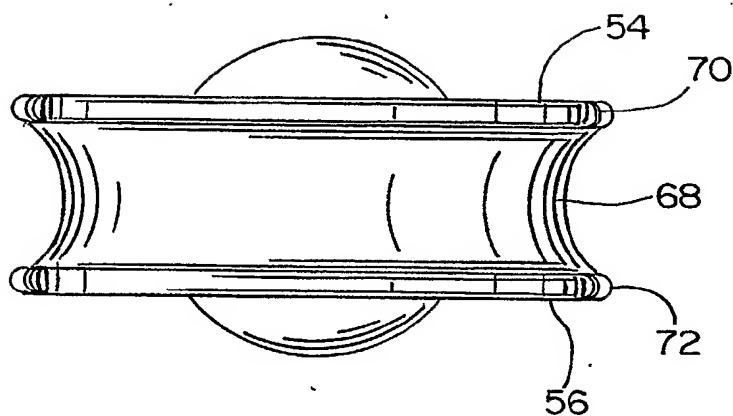


FIG. 5C

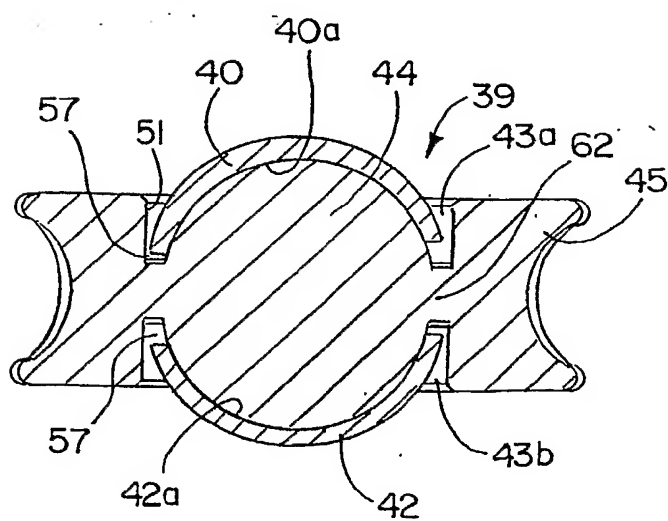


FIG. 5E

10/22

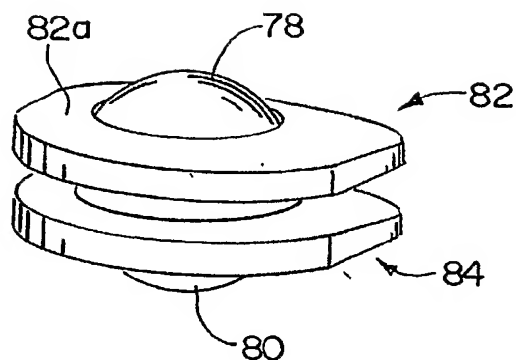


FIG. 6A

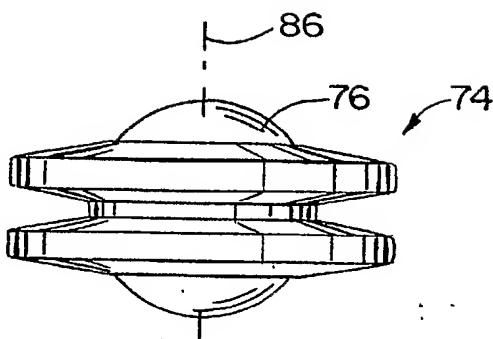


FIG. 6B

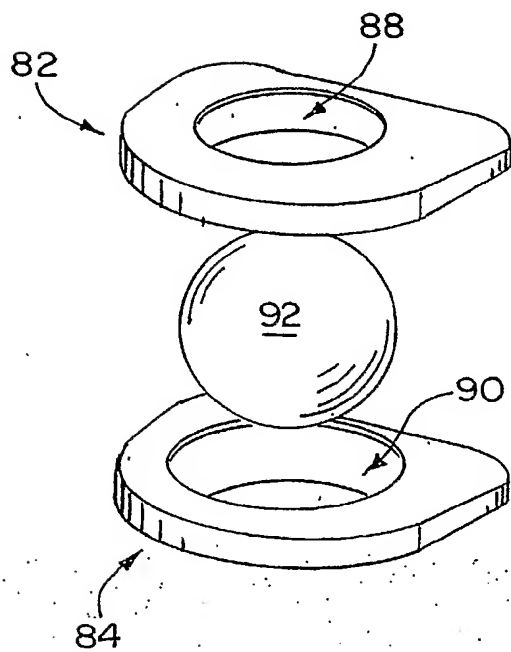


FIG. 6C

11/22

FIG. 6D

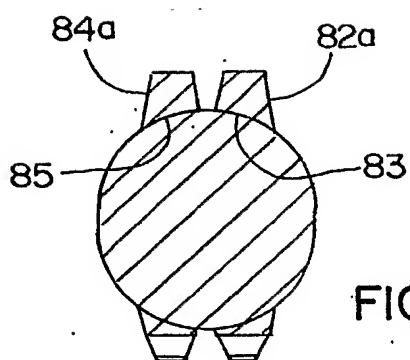
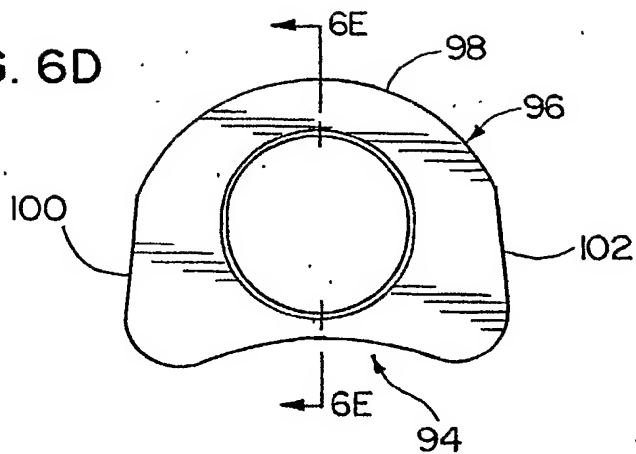


FIG. 6E

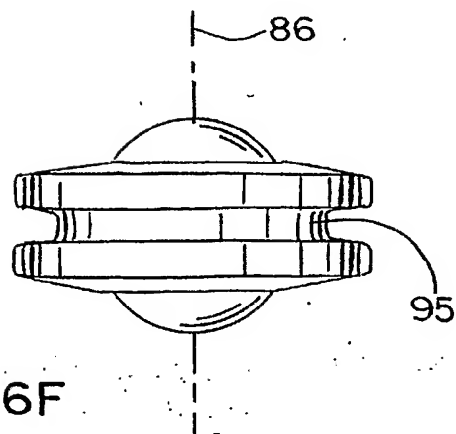


FIG. 6F

12/22

FIG. 7A

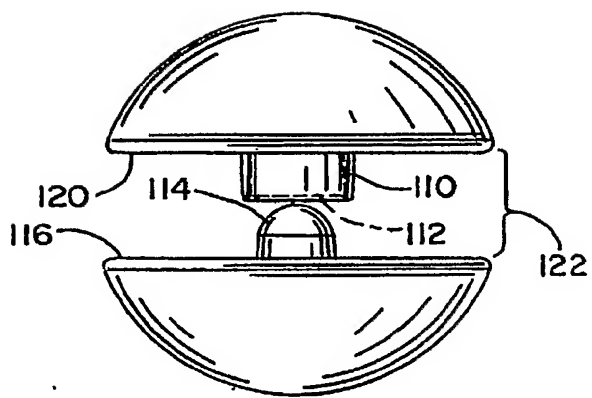
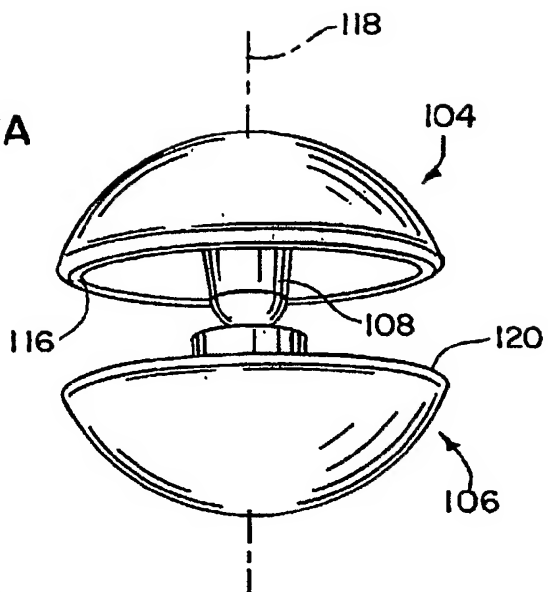


FIG. 7B

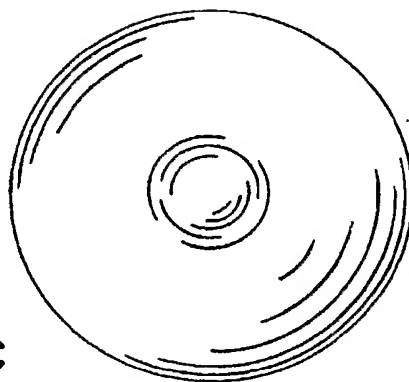


FIG. 7C

13/22

FIG. 8A

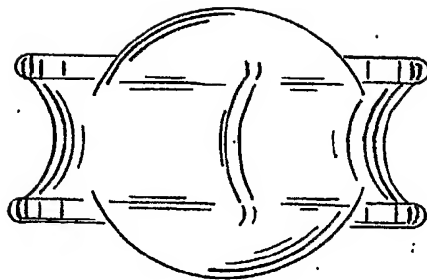
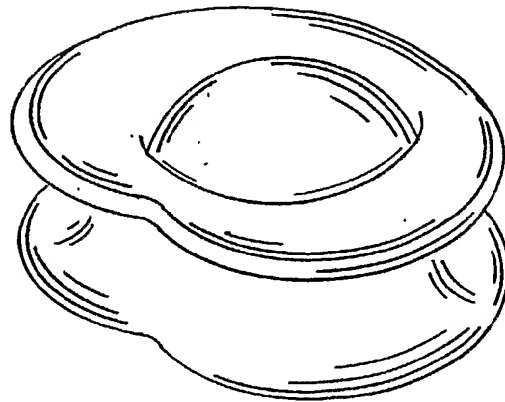


FIG. 8B

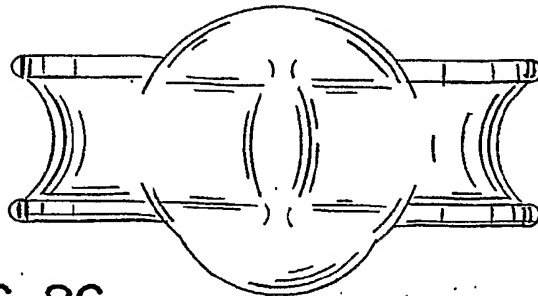


FIG. 8C

14/22

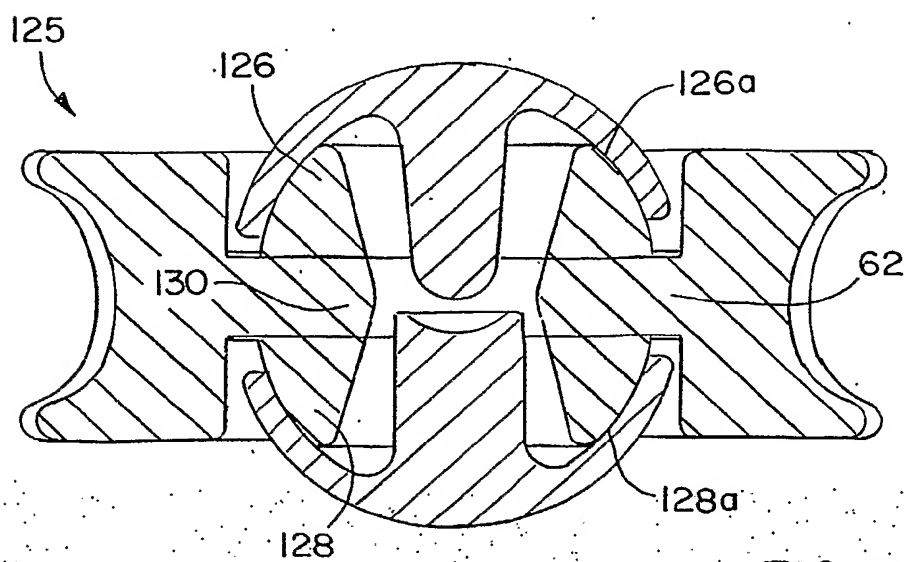
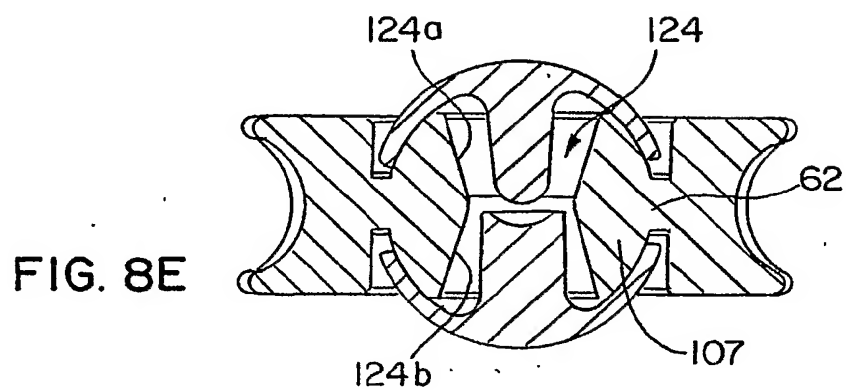
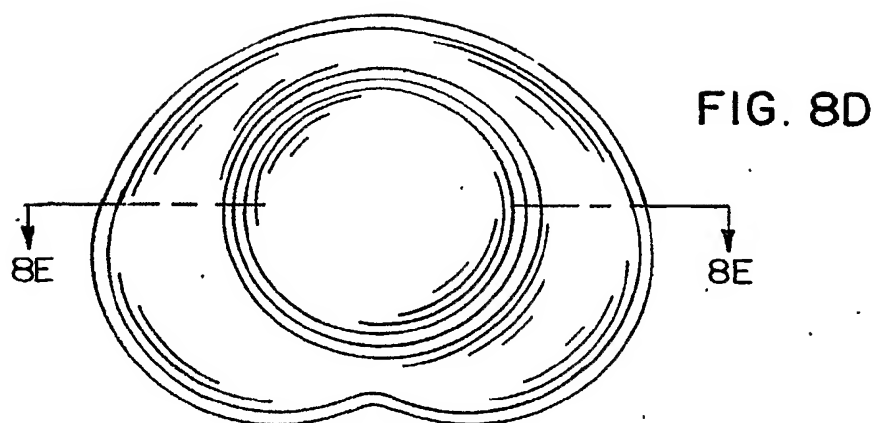


FIG. 9

15/22

FIG. 10A

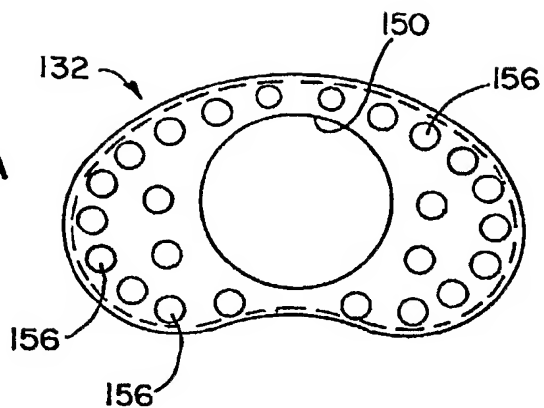


FIG. 10B

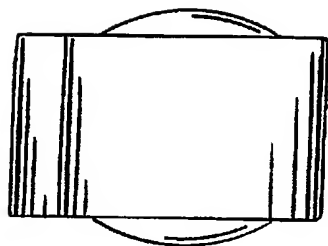


FIG. 10C

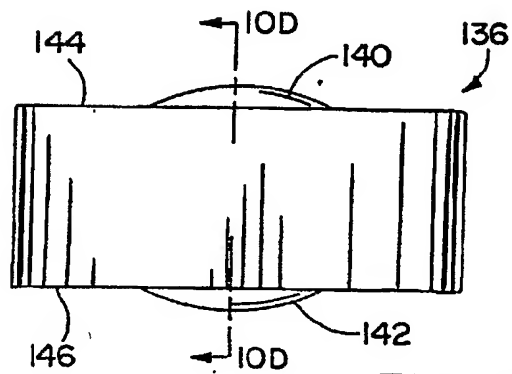
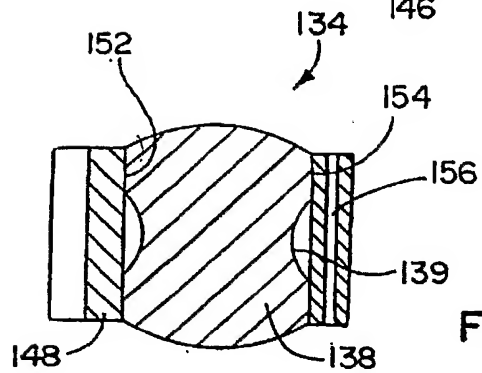


FIG. 10D



16/22

FIG. 10E

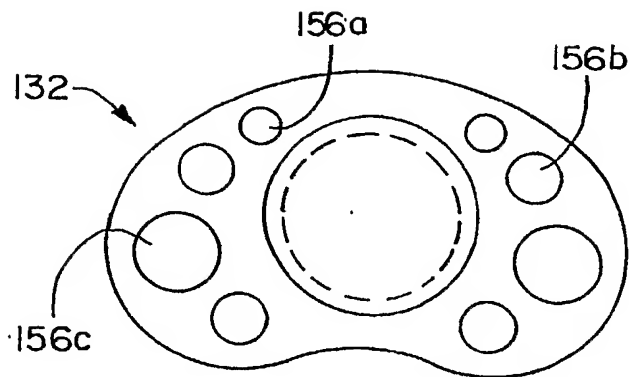


FIG. 10F

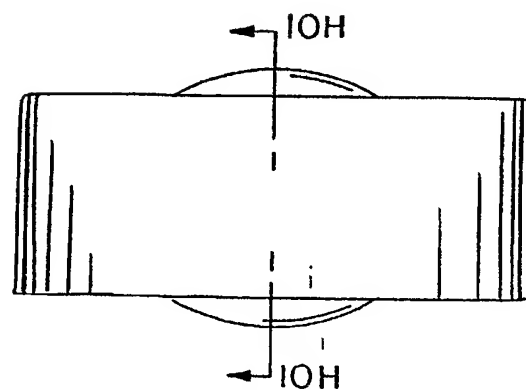
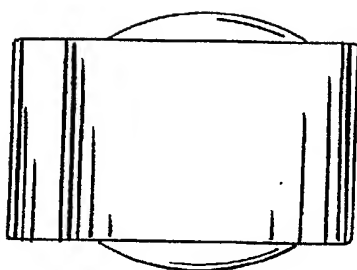


FIG. 10G

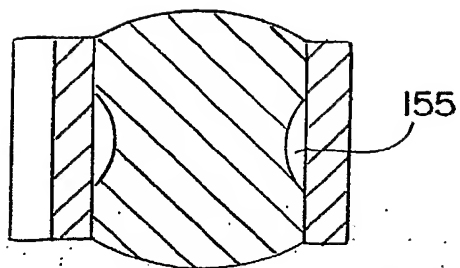


FIG. 10H

17/22

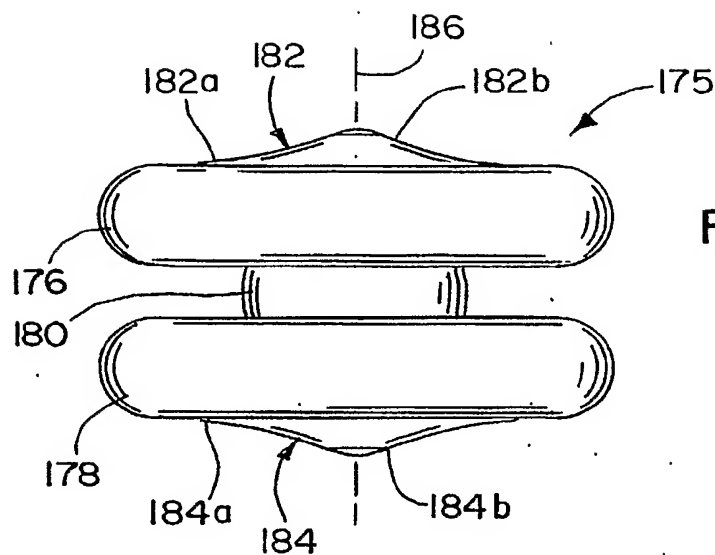


FIG. IIA

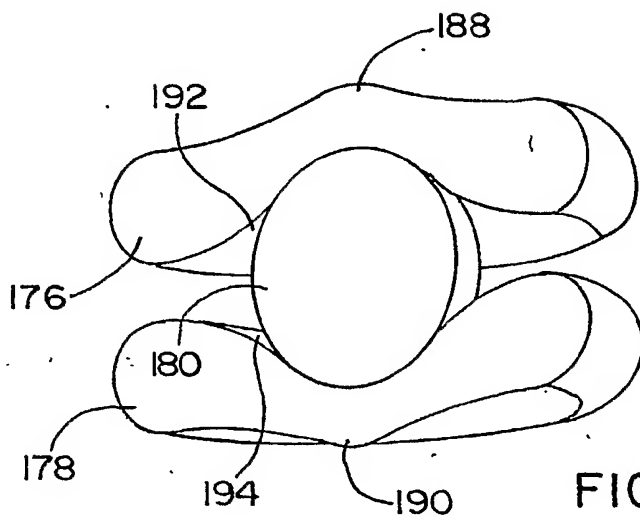


FIG. IIB

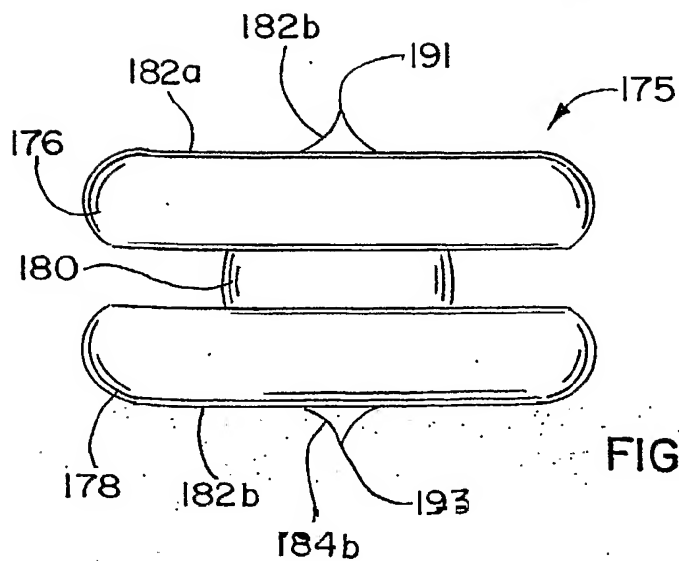


FIG. IIC

18/22

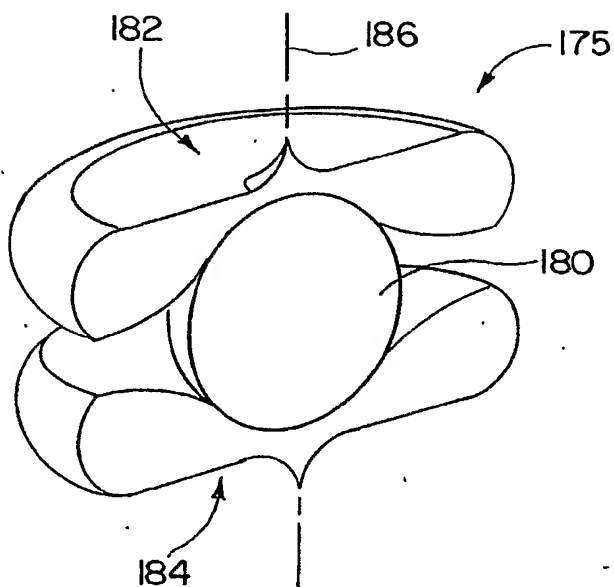


FIG. IID

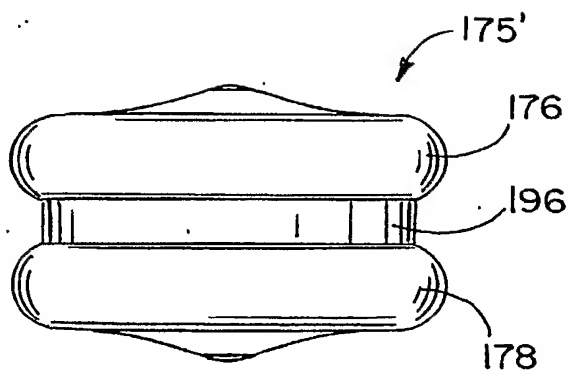


FIG. IIE

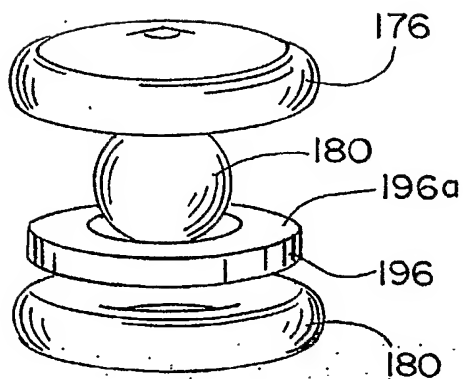


FIG. IIF

19/22

FIG. IIG

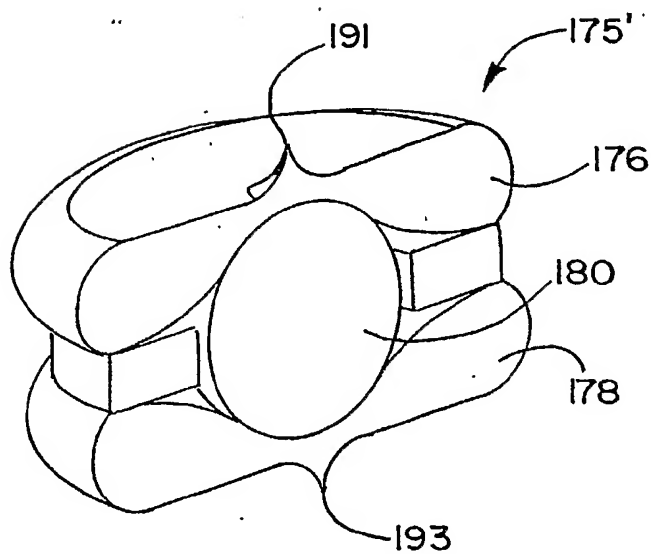
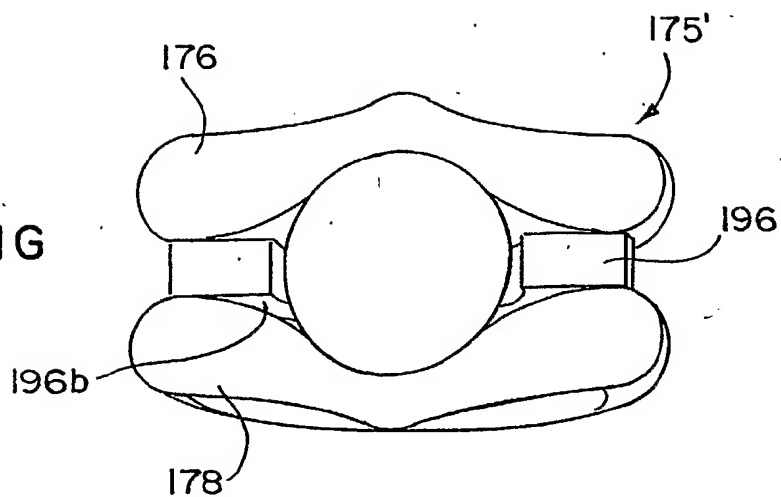


FIG. IIH

20/22

FIG.12B

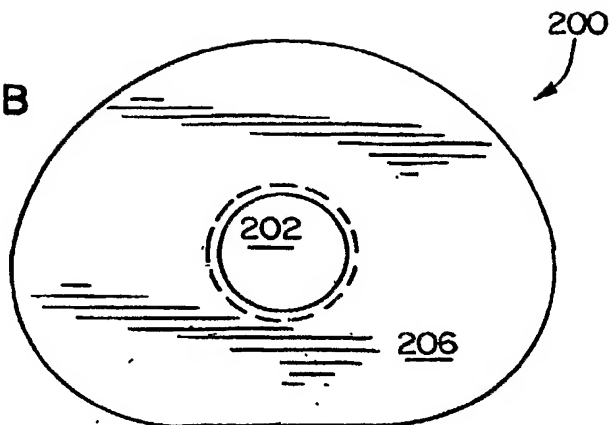


FIG.12A

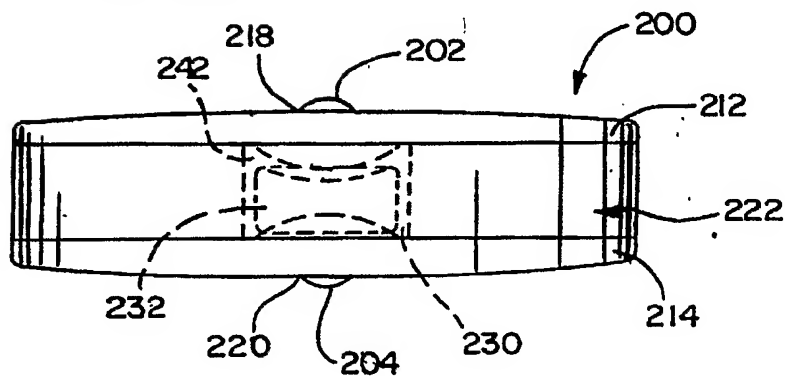
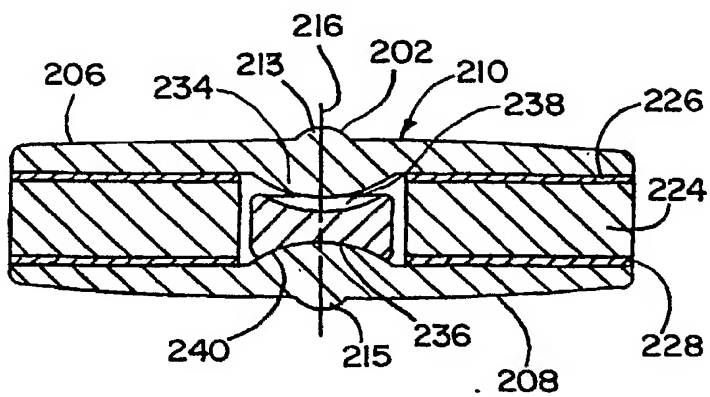
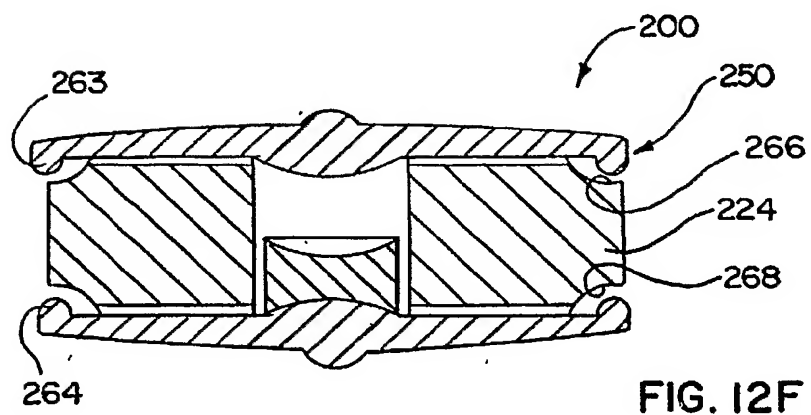
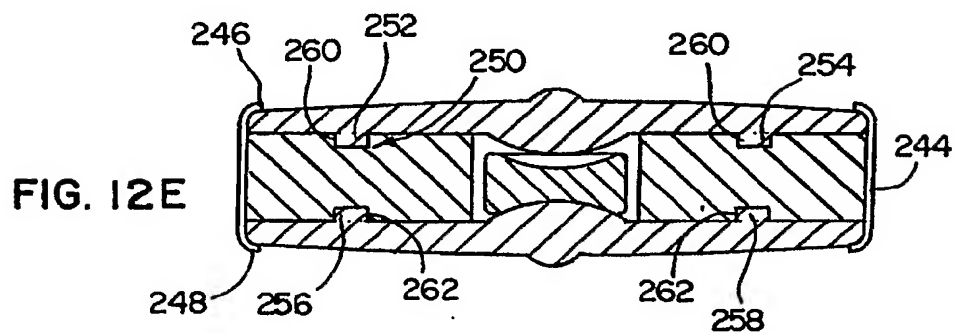
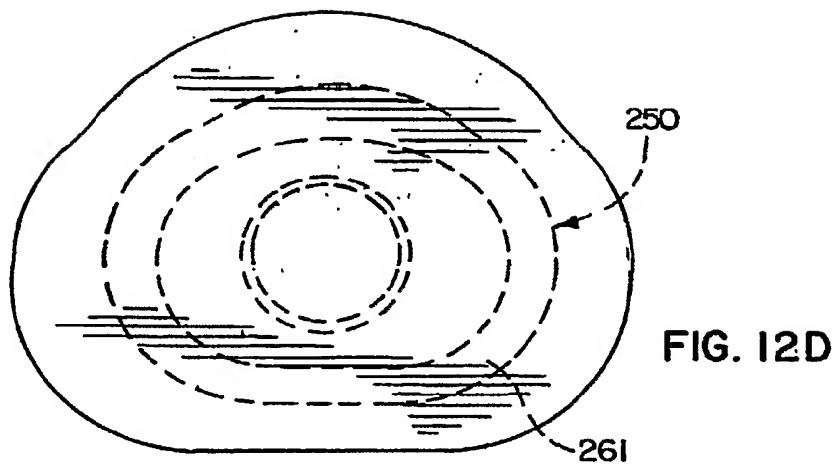


FIG.12C



21/22



22/22

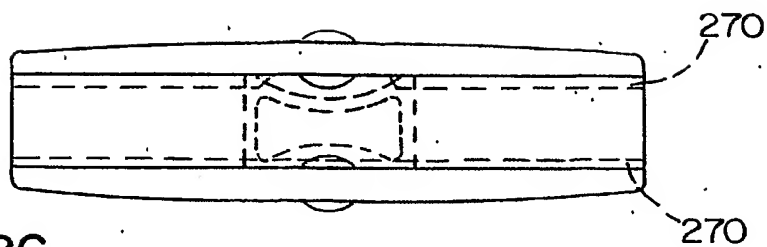


FIG. 12G

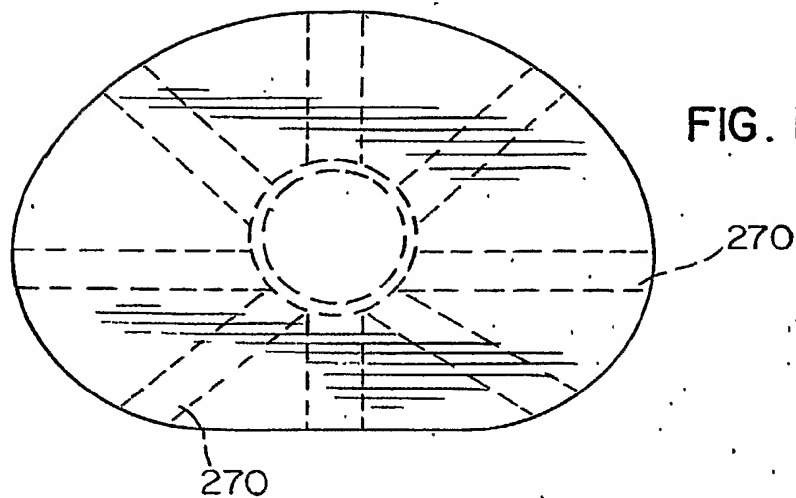


FIG. 12H

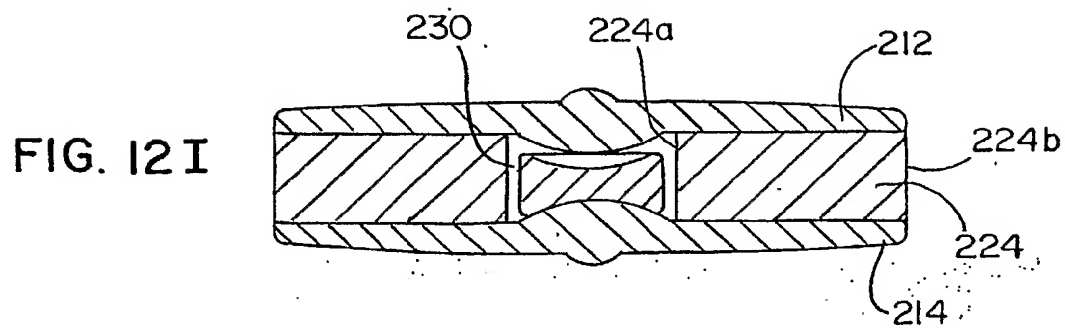


FIG. 12I

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/16394

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/44

US CL :623/17.14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/17.14

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,683,465 A (SHINN ET AL) 04 NOVEMBER 1997, see entire document.	1-63
A	US 6,478,822 A (LEROUX ET AL) 12 NOVEMBER 2002, see entire document.	1-63

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
12 AUGUST 2003	30 SEP 2003

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Box PCT
Washington, D.C. 20231
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Authorized officer

DAVID J ISABELLA

Deane Russell Job

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